

# Regulatory Road Map for Formaldehyde Emissions and other Hazardous Air Pollutants in Fiberglass Insulation Materials in the United States

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## **Abstract**

This paper provides a perspective of air pollution control regulations in the United States that affect the Wool Fiberglass Manufacturing Industry. In addition, it analyzes regulations specifically targeted towards formaldehyde emissions from these operations and evaluates what lies ahead under existing Clean Air Act requirements. This paper addresses only the regulatory climate in the United States. However, based on history, other countries such as Canada and European Union tend to mirror US laws that are eventually followed by other developing countries.

## **Clean Air Act Regulations in the United States**

The Clean Air Act (CAA) regulations in the United States date back to 1967 establishing gradually increasing emissions reductions and controls of stationary as well as mobile sources of air pollution. In 1990, US Congress drastically amended the Clean Air Act due to shortcomings in previous laws and to include new requirements to address environmental challenges. The 1990 amendments mandated significant new air quality programs and substantially revamped existing requirements.

One major new initiative under the 1990 CAA was the expansion to control emissions of Hazardous Air Pollutants (HAP). This includes National Emission Standards for Hazardous Air Pollutants (NESHAP), or maximum achiev-

able control technology (MACT) standards, as well as several related programs to enhance and support the NESHAP program.

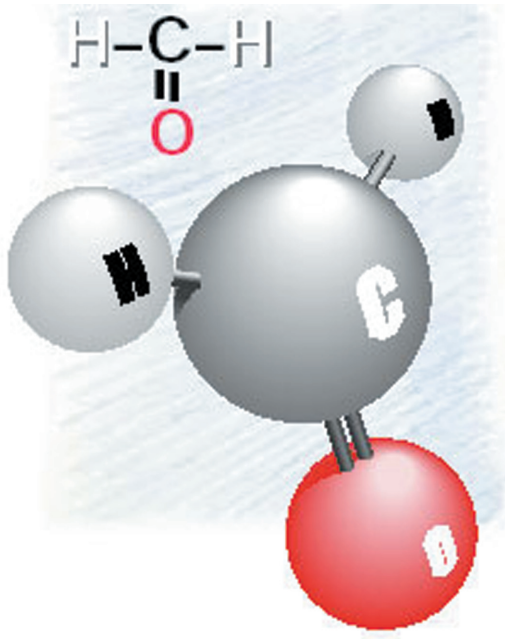
Section 112 of the Clean Air Act included a list of 189 chemicals and chemical compounds that are considered to be hazardous air pollutants. They are also known as air toxics; these are pollutants which are known or suspected to cause cancer or other serious health effects such as birth defects or reproductive effects. Formaldehyde and Phenol are included in this list of Hazardous air pollutants.

## **Why regulate Formaldehyde and sources using or producing formaldehyde?**

**FORMALDEHYDE (GAS) CAS No. 50-00-0** First Listed in the Second Annual Report on Carcinogens

## **CARCINOGENICITY**

Formaldehyde (gas) is reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals (IARC 1982, 1987, 1995). However, on June 14, 2004, an International Agency for Research on Cancer (IARC) Working Group recommended reclassification of Formaldehyde from a "probable" to a "known Carcinogen" based on studies of individuals exposed thirty to sixty years ago.



### The primary uses for formaldehyde

In the United States, Formaldehyde is used in production of urea-formaldehyde resins (23%), phenolic resins (19%), acetylenic chemicals (12%), polyacetal resins (11%), methylene diisocyanate (6%), pentaerythritol (5%), urea-formaldehyde concentrates (4%), hexamethylenetetramine (4%), melamine resins (4%), and miscellaneous products (chelating agents, trimethylolpropane, pyridine chemicals, nitroparaffin derivatives, textile treatments, and trimethylolethane) (12%). Urea-formaldehyde resins and phenol-formaldehyde resins are used primarily as adhesives in the manufacture of particle board, fiberboard, and plywood, and for molding, paper treating and coating, textile treating, surface coating, and foams for insulation. The percentage of total formaldehyde production used in urea-formaldehyde resins and phenol-formaldehyde resins have ranged between 20% and 26% each since the early 1960s (IARC 1982, 1995, ATSDR 1999).

### Major Sources of Formaldehyde Emissions

Combustion processes account for most of the formaldehyde released to the environment. These include automobile exhausts, power plants, incinerators, refineries, wood stoves, kerosene heaters, and cigarettes. Indirect sources include photochemical oxidation of hydrocarbons (especially methane) and other formaldehyde precursors released from combustion sources (IARC 1982, 1995, ATSDR 1999). According to EPA's Toxic Chemicals Release Inventory (TRI), annual environmental releases of formaldehyde totaled 17.2 million to 24.9 million lb between 1988 and 1999 with the majority (50% to 66%) released to the atmosphere. Releases for 1999 were approximately 24.2 million lb from 849 facilities; however, the top two facilities accounted for 42% of the total (TRI99 2001).

Clean Air Act Regulations in the United States Affecting Wool Fiberglass Insulation Manufacturing Operations

### New Source Performance Standards (NSPS):

The 1970 CAA under Section 111 required the EPA to promulgate emission standards of performance for new sources that cause, or contribute significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare. One such industrial sector regulated under the NSPS regulations is the Wool Fiberglass Insulation Manufacturing.

Pursuant to this CAA requirements, EPA promulgated the first source specific regulation affecting any new or modified Fiberglass Insulation Manufacturing Plants that commenced construction, modification, or reconstruction after February 7, 1984.

According to EPA's background document regarding the Wool Fiberglass Manufacturing, there are potential emissions of Particulates, Phenol and Formaldehyde from this source category. However, the EPA regulated just particulate emissions and the NSPS did not require controls of organic emissions. This regulations in 40 CFR 60, Subpart PPP and Section § 60.682 restrict discharge into the atmosphere from any affected facility any gases which contain particulate matter in excess of 5.5 kg/Mg (11.0 lb/ton) of glass pulled.

### 1990 Clean Air Act Amendments

As stated earlier, the 1990 CAA drastically changed the air pollution control regulations in the US by requiring controls of 189 chemical substances that are considered to be hazardous or toxic in order to protect the human health and the environment.

### List of Source Categories

Section 112(c) of the Clean Air Act requires that EPA publish and regularly update a listing of all categories and subcategories of major and area sources that emit HAPs. The list of source categories itself is not contained in the CAA; it was initially published in the Federal Register on July 16, 1992 (56 FR 31576). Since the Act includes Formaldehyde as a hazardous air pollutant, EPA must identify categories of sources that release this listed hazardous air pollutant. The air toxics emitting sources are to be identified as major (large) or area (small) sources. Specific categories of sources listed due to Formaldehyde emissions include, Wool Fiberglass Manufacturing; Plywood and Composite Wood Products; Wetformed fiberglass mat production; Combustion operations such as stationary gas Turbines, etc.

### Maximum Achievable Control Technology (MACT) Emission Standards

Section 112(d) of the CAA requires EPA to promulgate regulations establishing emission standards for each category or subcategory of major sources and area sources of HAPs [listed pursuant to Section 112(c)]. The standards must require the maximum degree of emission reduction that the EPA determines to be achievable by each particular source category. Different criteria for MACT apply for new and existing sources. Less stringent standards, known as generally available control technology (GACT) standards, are allowed at the Administrator's discretion for area sources.

**EMISSIONS STANDARDS REQUIRED IN THE FINAL SUBPART NNN REGULATIONS.  
COMPLIANCE DATE TO MEET THESE LIMITS IS JUNE 14, 2002 FOR EXISTING FACILITIES  
AND UPON STARTUP FOR NEW FACILITIES.**

<b>Source</b>	<b>Pollutant</b>	<b>Emissions Standards</b>
New and Existing Glass melting Furnace	PM	0.5 pounds/ton glass pulled
Existing RS Line	Formaldehyde	1.2 lbs/ton glass pulled
New RS Line	Formaldehyde	0.8 lbs/ton glass pulled
New FA Line producing heavy density wool fiberglass.	Formaldehyde	7.8 lbs/ton glass pulled
Existing or New FA line producing pipe product wool fiberglass.	Formaldehyde	6.8 lbs/ton glass pulled

**Schedule for MACT Standards and Review**

Pursuant to Section 112(e) of the Act EPA published specific schedules for promulgating the MACT standards. The Wool Fiberglass Manufacturing is listed in the 7-year group and EPA promulgated the MACT standard for this source category in 1999, two years behind schedule.

**MACT Standard for Wool Fiberglass Manufacturing**

On June 14, 1999, USEPA promulgated the National Emissions Standards for Hazardous Air Pollutants for Wool Fiberglass Manufacturing Operations. This regulations, called MACT standards, can be found at 40 CFR 63, Subpart NNN. This rule affects all existing and new wool fiberglass manufacturing plants located anywhere within US that are major sources for emissions of Hazardous Air Pollutants (HAPs). Major source is defined as a facility that emits or has a potential to emit, after taking into consideration air pollution controls, 10 tons or more per year of any single HAP or 25 tons or more per year of any combination of HAPs.

**Affected Wool Fiberglass Manufacturing Operations**

This rule in Subpart NNN applies to following existing and newly constructed operations located at a wool fiberglass manufacturing facility:

- All glass melting furnaces
- Rotary Spin (RS) manufacturing lines that produce bonded building insulation

- Flame Attenuation (FA) manufacturing lines that produce bonded pipe insulation.

*Following new sources:*

- FA manufacturing lines that produce bonded heavy density products.

*Exemptions from Subpart NNN requirements:*

- RS and FA lines that produce nonbonded products, where no binder is applied.
- A facility emitting less than 10 TPY of any single HAP or less than 25 TPY of any combination of HAPs. (Minor or Area Source).
- Facilities that manufacture mineral wool from rock or slag.

Pursuant to Subpart NNN, the rule expected to reduce HAP and other emissions as follows in *Table 1*:

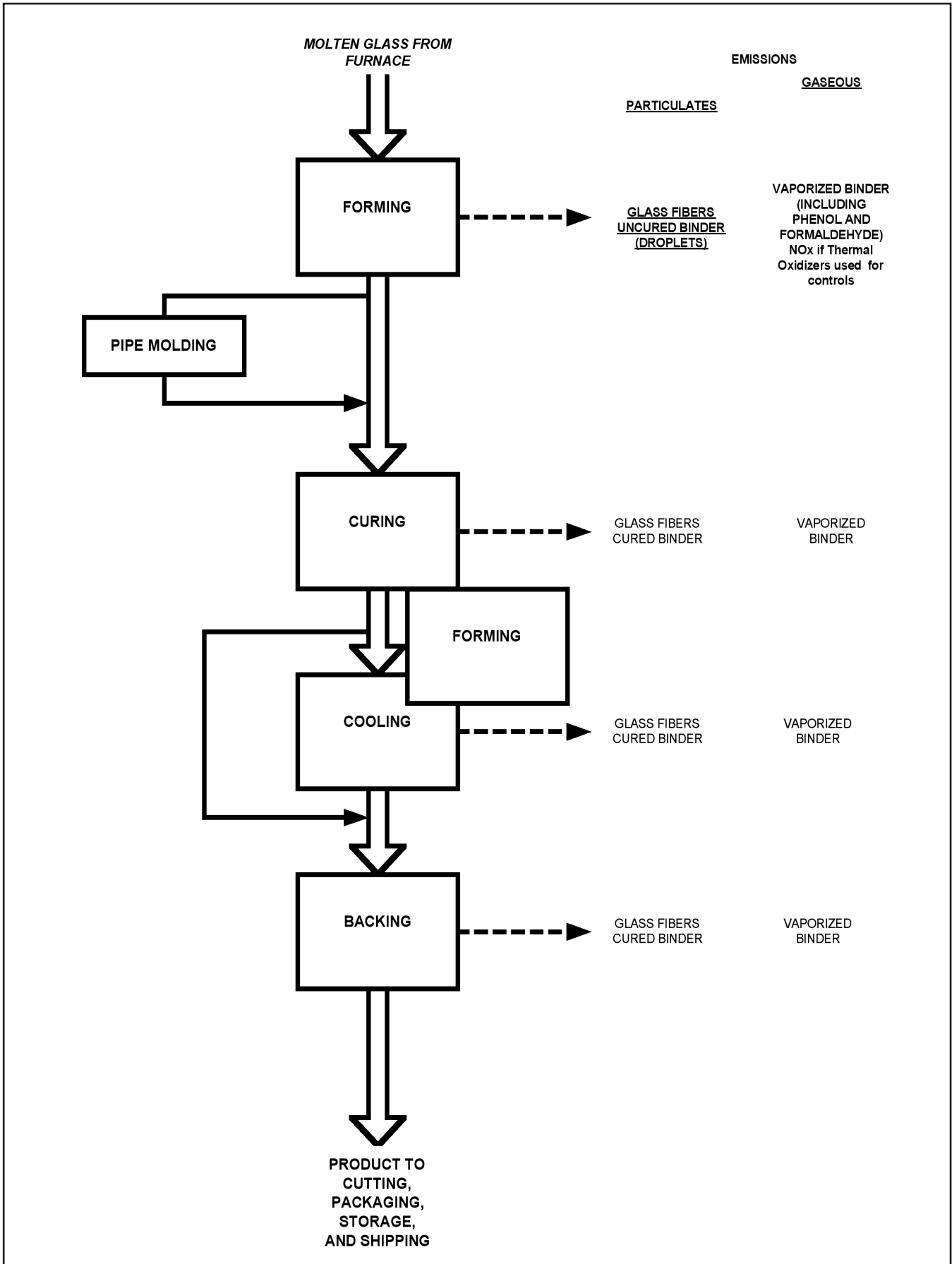
**What is Next After the Implementation of MACT Standards?**

**1. RESIDUAL RISK**

Section 112(f) of the Clean Air Act amendments of 1990 requires EPA to assess the risk to public health remaining after the implementation of MACT standards. If the "Residual Risk" for a source category does not protect public health with "an ample margin of safety" (AMOS), then EPA must promulgate human health based standards for that source category to

TABLE 1

<b>Source</b>	<b>Pollutant</b>	<b>Baseline emissions (tons/year)</b>	<b>Projected Emission Reduction (ton/yr)<sup>a</sup></b>
Glass-Melting Furnaces	Metal HAP	0.3	0.01
	Particulate Matter (PM)	830	840
RS Manufacturing Lines	Formaldehyde	1350	580
FA Manufacturing Lines	Formaldehyde	600	0
All Sources	Total HAPs	1950	580
	PM (Non-HAP)	830	840
	<b>Total Pollutants</b>	<b>2780</b>	<b>1420</b>



further reduce HAP emissions. As noted earlier, EPA estimated that only 30% of Formaldehyde emissions would be reduced by installing MACT controls at Wool Fiberglass Manufacturing operations. If this is indeed the level of actual Formaldehyde reductions achieved in the industry and if there remains 70% uncontrolled emissions, then Residual Risk analysis may indicate additional control requirements to protect human health and the environment.

This Human Health Standard requires EPA to evaluate remaining risk after implementation of MACT controls to a category or subcategory of sources emitting HAPs. If controls for listed hazardous chemicals, that are known or probable or possible human carcinogens, from such source categories do not reduce lifetime cancer risks to individual most exposed to less than one in one million, then the CAA requires EPA to promulgate additional health based standards for such source category. This means, even if one facility under the wool fiberglass manufacturing industry subject to the MACT standards exceeds the one in one million cancer risk for Formaldehyde, a suspect carcinogen, then EPA is required to promulgate residual risk standard for all affected facilities in the category.

In order to prevent adverse Ecological Risks, the EPA is required to set more stringent standards, if necessary, to prevent adverse environmental effects, taking into consideration costs, energy, safety, and other relevant factors. The EPA must set Residual Risk standards within 8 years after promulgation of the MACT standards. Therefore, EPA must evaluate remaining risk for Wool Fiberglass Manufacturing operations and if necessary develop residual risk Standard for Wool Fiberglass Manufacturing by June 14, 2007.

### **Criteria for evaluating Residual Risk**

EPA's residual risk program includes a framework for risk assessments of human risk and ecological risk.

#### *Framework for EPA's Human Health Risk assessment*

- Hazard Identification. The first step in a risk assessment is to determine whether the pollutants of concern can be causally linked to the health effects in question (cancer and/or non-cancer). Factors such as the route of exposure, the type and quality of the effects, the biological plausibility of findings, the consistency of findings across studies, and the potential for bioaccumulation all contribute to the strength of the hazard identification statement.

- Dose-response Assessment. This step is the quantitative characterization of the relationship between the concentration, exposure, or dose of a pollutant and the resultant health effects. When adequate data exist, the typical end product of the dose-response assessment for non-cancer effects is the identification of a sub-threshold dose or exposure level that humans could experience daily for a lifetime without appreciable probability of ill effect. Sub-threshold short-term exposure levels are also under development. For cancer, the typical goal of this step is estimation of a full dose-response curve for

low exposures.

- Exposure Assessment. EPA's current Guidelines for Exposure Assessment, published in 1992, provide the framework for this step. An exposure assessment for air toxics has four major components: (1) emissions characterization; (2) environmental fate and transport analysis; (3) characterization of the study population; and (4) exposure characterization for both inhalation and non-inhalation pathways.

- Risk Characterization. This step is where all the information from the previous steps is integrated to describe the outcome of the analysis, and where the uncertainty and variability in the results are described. EPA's 1995 Guidance for Risk Characterization is the foundation for this step of the process.

#### *Framework for EPA's Ecological Risk Assessment*

- Problem Formulation. In this phase, the problem is defined, the purpose of the risk assessment is articulated, and a plan for characterizing the risks is developed. Important steps include identifying assessment endpoints, developing the conceptual model, and preparing an analysis plan.

- Analysis. This phase involves evaluating how exposure to stressors might occur (characterization of exposure) and the relationship between stressor levels and ecological effects (characterization of effects).

- Risk Characterization. In this phase, the risk is estimated and described through integration of the exposure and ecological effects profiles generated in the analysis phase.

### **Data for Human Health Risk Assessment.**

For human health risk assessments, EPA's preferred source of information is the

Agency's Integrated Risk Information System (IRIS). EPA will consult other agency and outside sources as needed to augment its data. As assessments for some HAPs may be less current than others, the Agency will evaluate the appropriateness of these assessments in light of more recent credible and relevant information. The role of IRIS in risk assessment is that it is used as a tool that provides hazard identification and dose-response assessment information, but it does not provide situational information on individual instances of exposure. Combined with facility specific exposure information, the data in IRIS can be used in evaluating public health risks of a particular chemical. This information can then be used to develop risk management process, such as pollution control regulations, to protect public health with ample margin of safety.

### **Selection of Chemical Substances for IRIS**

EPA develops a list of substances for IRIS assessment on an annual basis. Chemicals are selected based on one or more of the following factors: (1) Agency statutory, regulatory, or program implementation need; (2) the availability of new scientific information or methodology that might significantly change current IRIS information; (3) interest to other levels of government or the public; (4) most of the scientific assessment work has been completed while meeting other Agency

requirements, and only a modest additional effort will be needed to complete the review and documentation for IRIS.

### Current IRIS data for Formaldehyde.

The current information and dose-response value for formaldehyde in IRIS is based on a 1987 study. EPA acknowledged that significant new data and analysis have become available since that time such as the work conducted by the CIIT Centers for Health Research (formerly, the Chemical Industry Institute of Toxicology). EPA is evaluating CIIT information and other recent information in the reassessment of Formaldehyde unit risk estimate. EPA plans to bring this reassessment to be reviewed by the Science Advisory Board and update the IRIS for Formaldehyde in the summer of 2004. In addition, EPA acknowledged that it should consider Formaldehyde as a carcinogen and its dose-response values for carcinogenicity is likely to change. \*\*

### New Health Effect Information related to Formaldehyde

On June 20, 2004, the International Agency for Research on Cancer (IARC), part of the World Health Organization, announced that the working group, convened by the IARC Monographs Programme, concluded that Formaldehyde is Carcinogenic to humans. Previous evaluations, based on smaller number of studies available at that time had concluded that Formaldehyde was probably carcinogenic to humans, but new information from studies of persons exposed to Formaldehyde has increased the overall weight of the evidence. Therefore, IARC upgraded Formaldehyde to a Category 1 (known human) carcinogen from 2A (probable human) carcinogen.

Based on this new information from IARC, the expert working group has determined that there is now sufficient evidence that formaldehyde causes nasopharyngeal cancer in humans, a rare cancer in developed countries. The working group also found limited evidence for cancer of the nasal cavity and paranasal sinuses and strong but not sufficient evidence for leukaemia.

### Potential Impact of IARC findings in EPA's Residual Risk Rulemaking

The Integrated Risk Information System (IRIS), prepared and maintained by the USEPA, is an electronic database containing information on human health effects that may result from exposure to various chemicals in the environment. Since EPA has already scheduled to review new information and update data regarding Formaldehyde, the new information from IARC would compel EPA to evaluate any new data on which IARC made this decision. Upon further review EPA and may revise the carcinogenicity of Formaldehyde. This could require a peer review of available data and could lead to revision to exposure and concentration levels to protect public health with ample margin of safety. As the result, new health risk values will be developed to assess effect on public health from MACT controlled facilities including wool fiberglass manufacturing operations. Any lowering of risk value could show potential risk from wool fiberglass manufacturing

in excess of one in one million cancer risk on most exposed individual. If high levels of risk is shown, this would require EPA to promulgate regulations to further reduce Formaldehyde emissions from affected source category.

### 2. 8-YEAR MACT REVIEW

Section 112(d)(6) of the Act states "The EPA shall review and revise as necessary, taking into consideration development in practices, processes, and control technologies, emission standards promulgated under this section no less often than every 8 years." This means, EPA must review already promulgated MACT standards every 8-years. This review is to focus on new source standards and not ratcheting down on existing sources. EPA plans to conduct this 8-year review simultaneously with Residual Risk.

### 3. URBAN AIR TOXICS STRATEGY

Section 112(k) of the Clean Air Act includes programs to substantially reduce HAP risks in urban areas. Under the Urban Air Toxics Strategy, EPA is developing standards to control toxic air pollutants from area sources. "Area" sources are those sources that emit less than 10 tons annually of a single hazardous air pollutant or less than 25 tons or more annually of a combination of hazardous air pollutants. The Clean Air Act (CAA) requires EPA to identify a list of at least 30 air toxics that pose the greatest potential health threat in urban areas, and for the Strategy, EPA identified a list of 33 air toxics. The CAA also requires EPA to identify and list the area source categories that represent 90 percent of the emissions of the 30 "listed" air toxics and subject them to standards under the CAA (section 112(d)). Through three separate listings (including a list in the Urban Air Toxics Strategy), EPA has identified a total of 70 area source categories which represent 90 percent of the emissions of the 30 listed air toxics. Of these 70 area source categories, 14 have been regulated and the remaining area source standards are under development or will be developed in the future.

### EPA's list of 33 Air Toxics Under the Urban Air Toxics Strategy includes:

Acetaldehyde; Acrolein; Acrylonitrile; Arsenic Compounds; Benzene; Beryllium Compounds; 1,3 - butadiene; Cadmium Compounds, Carbon Tetrachloride; Chloroform; Chromium Compounds, Coke Oven emissions, 1-2 dichloropopene; Diesel Particulate Emissions; Ethylene Dibromide; Ethylene Dichloride; Ethylene Oxide; Formaldehyde; Hexachlorobenzene; Hydrazine; Lead Compounds; Manganese Compounds; Mercury Compounds; Methylene Chloride; Nickel Compounds; perchloroethylene; polychlorinated biphenyls (PCBs); Polycyclic organic matter (POM); propylene dichloride; Quinoline; 1,1,2,2- Tetrachloroethane; Trichloroethylene; Vinyl Chloride.

### 4. AREA WIDE ACTIVITIES

Section 112(k)(4) of the Act requires EPA to support area wide strategies developed by State or local air pollution control agencies that are intend-

ed to reduce risk from emissions by area sources within a particular area. Under this program state or local agencies may target a particular urban area and a particular chemical of concern.

## 5. INDOOR AIR QUALITY

US EPA and States such as California have published guidelines to reduce exposure to toxic chemicals indoors, including private residences and public buildings, specifically schools. These guidelines list Formaldehyde as one of the chemicals of concern in indoor air quality studies.

Major Sources of indoor Formaldehyde emissions are pressed wood products made with urea-formaldehyde resins, building materials, and furnishings. Insulation materials are considered as minor sources of formaldehyde emissions, but still may contribute to overall exposure to formaldehyde indoors. Although no specific regulations are in effect at this time, there are several guidance material available from the US EPA and California Air Resources Board to reduce overall formaldehyde emissions indoors by substituting products that are formaldehyde free or contain very low levels. In addition Consumer Product Safety Commission also provide recommendations to reduce potential formaldehyde exposures indoors.

## 6. OTHER POTENTIAL REGULATIONS:

USEPA just promulgated regulations to implement the 8-hour Ozone NAAQS standard and moving away from the 1-hour ozone standard that has been used for the past 3 decades. This change in NAAQS resulted in designating more than 450 counties in the US as non-attainment for Ozone. This change would require states to promulgate regulations to reduce VOC and NO<sub>x</sub> emissions that are precursors to Ozone formation.

Wool Fiberglass manufacturing facilities have traditionally installed Thermal Oxidizers to control formaldehyde emissions to meet the MACT standards. However, Thermal Oxidizers emit NO<sub>x</sub> emissions due to combustion processes. Therefore, states may require reductions in both Formaldehyde and NO<sub>x</sub> emissions from facilities that are located in these designated non-attainment areas.

## Conclusion

It is evident from this presentation that there are very difficult, uphill and uncertain regulatory path ahead for the Wool Fiberglass Manufacturing Operations in the US. These are predominantly due to health based risk associated with use of resin binders containing Formaldehyde and continuing requirements to reduce ozone forming chemicals such as Formaldehyde and NO<sub>x</sub>. Pollution prevention activities such as use of formaldehyde free chemicals and minimizing use of formaldehyde may be required to reduce impact from future regulations. These alternatives would be feasible provided product quality and performance of insulation materials are not adversely affected.

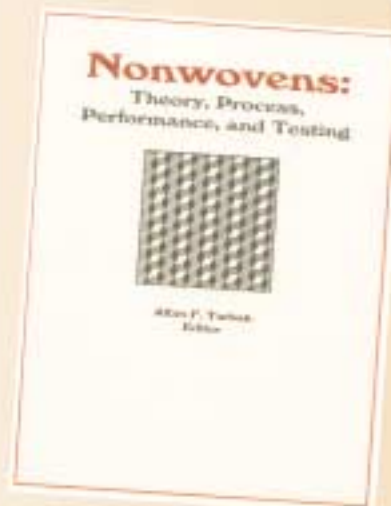
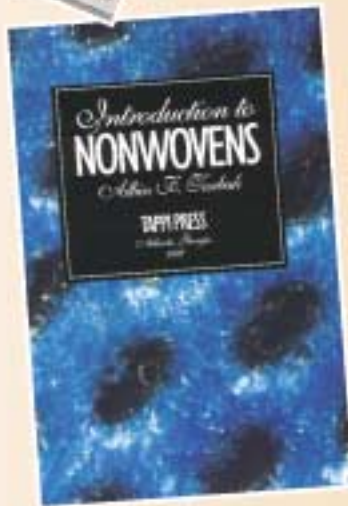
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\*\* National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; Effluent Limitations Guidelines and Standards for the Timber Products Point Source Category; List of Hazardous Air Pollutants, Lesser Quantity Designations, Source Category List. — INJ

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