

Toxics Use Reduction Institute

Summary of Policy Analysis

*Higher Hazard Substance Designation Recommendation:
Formaldehyde (CAS # 50-00-0)*

The Toxics Use Reduction Institute recommends that formaldehyde be designated as a Higher Hazard Substance. This Policy Analysis presents the factors the Institute has taken into account in developing these recommendations.

1. State of the Science

Formaldehyde is known to have both acute and chronic effects on human health. Acute health effects from exposure can include coughing, wheezing, chest pains, bronchitis, severe skin burns, contact dermatitis, and throat, nose, eye and skin irritation. The International Agency for Research on Cancer (IARC) classifies formaldehyde in Group 1 (carcinogenic to humans). Formaldehyde exposure is also associated with development of asthma.

2. Number of Facilities Affected

The TURA program estimates that between 10 and 25 facilities would be affected by the lower reporting threshold of 1,000 lb for formaldehyde.

3. Opportunities for New Filers

The availability of alternatives in custom paper, coated paper and resins, as well as other common uses of formaldehyde, provide an opportunity for facilities to reduce or eliminate their use of formaldehyde. There are also important opportunities for outreach to facilities that are not required to file under TURA, but use formaldehyde in ways that are likely to lead to significant worker exposures. Furthermore, there may be opportunities to use the techniques and approaches of green chemistry and of biomimicry to identify alternative approaches to manufacturing resins using renewable resources.

4. Regulatory Context

Formaldehyde is subject to numerous federal regulations. It is reportable under the Toxic Release Inventory (TRI) and listed as a hazardous air pollutant under the Clean Air Act (CAA). The federal Formaldehyde Standards for Composite Wood Products Act of 2010 sets standards for formaldehyde emissions from composite wood products. In California, formaldehyde is regulated as a carcinogen under the Safe Drinking Water and Toxics Act of 1986 (Proposition 65). The New Jersey Worker and Community Right to Know Act requires facilities using 500 lb or more of formaldehyde to report their total use, emissions, and pollution prevention activities. Formaldehyde is also subject to Massachusetts Right-to-Know standards. Maine's Department of Environmental Protection has listed formaldehyde as a hazardous air pollutant with a reporting threshold of 1,000 lb. Internationally, formaldehyde is listed as a dangerous substance and is

subject to Annex VI Classification, Labeling and Packaging (CLP) regulation by the European Chemicals Agency (ECHA). The Swedish Chemical Agency (KemI) and Japan's Building Standard Law regulate formaldehyde in wood products and other building materials.

5. Implications for the TURA Program

The TURA program has a variety of resources to offer facilities working to reduce or eliminate their use of formaldehyde in production. The program can also help address formaldehyde exposures in small businesses and institutions that are not covered under TURA, such as mortuaries, cosmetology training schools, and hospitals. The fact that formaldehyde is used in a wide variety of applications may pose some challenges, and there is a need for research and development on safer alternatives for specific applications, such as the manufacture of resins.

6. Paraformaldehyde

The Advisory Committee recommended that paraformaldehyde be considered along with formaldehyde. The Science Advisory Board has recommended that paraformaldehyde remain uncategorized (and thus not be put forward with formaldehyde as a Higher Hazard Substance). TURI supports this recommendation; although other policy approaches would also be reasonable, TURI believes that making no change to the status of paraformaldehyde is the best option for the TURA program at this time.

Toxics Use Reduction Institute

POLICY ANALYSIS

***Higher Hazard Substance Designation Recommendation:
Formaldehyde (CAS # 50-00-0)***

The TURA Science Advisory Board (SAB) has recommended designating formaldehyde as a higher hazard substance under TURA. With this designation, the reporting threshold for formaldehyde use would be lowered to 1,000 lbs/year for companies in TURA-covered industry sectors with ten or more employees. Companies entering the program under the lower reporting threshold would be required to file annual toxics use reports, pay an annual toxics use fee, and develop a toxics use reduction plan every two years. In addition, the TURA program would prioritize formaldehyde in allocating resources, providing targeted assistance to facilities working to reduce or eliminate use of formaldehyde.

This policy analysis summarizes key scientific information on formaldehyde, estimates the number of facilities that are likely to enter the program as a result of the lower reporting threshold, analyzes opportunities and challenges that new filers are likely to face, and discusses the implications of this policy measure for the TURA program. Based on this analysis, the Toxics Use Reduction Institute (TURI) supports the SAB's recommendation that formaldehyde be designated as a higher hazard substance.

1. State of the Science

Formaldehyde is available in multiple forms. These include formaldehyde gas, formalin solution (formaldehyde dissolved with methanol in water), trioxane, and paraformaldehyde (a polymerized form of formaldehyde). Trioxane and paraformaldehyde have separate CAS numbers. Formaldehyde may be provided in any of these forms, but is typically transported and distributed as formalin solution or, less often, as paraformaldehyde. Manufacturers desiring formaldehyde gas as inputs for resins or other products then process the formalin or paraformaldehyde to release the formaldehyde. Paraformaldehyde is discussed in more depth in section 6.

Formaldehyde is known to have both acute and chronic effects on human health. In 2006, the International Agency for Research on Cancer (IARC) reclassified formaldehyde from Group 2A (probably carcinogenic to humans) to Group 1 (carcinogenic to humans). Formaldehyde exposure is also associated with development of asthma.¹ The primary route of exposure to formaldehyde is through inhalation but in liquid form formaldehyde can also be absorbed through the skin.² People are exposed to formaldehyde through both occupational and environmental exposures. Environmental exposure to formaldehyde occurs through industrial emissions and waste, fertilizers, and food, as well as through consumer products and indoor air in buildings made with or containing materials which have formaldehyde as a component.³

The U.S. EPA estimates that exposure to formaldehyde is not expected to be of concern to terrestrial and aquatic environments. In water, formaldehyde readily biodegrades to low levels. Formaldehyde does not bioaccumulate in aquatic organisms.⁴

On June 2, 2010, U.S. EPA released its draft toxicological review of formaldehyde – inhalation assessment.⁵ On April 8, 2011, the National Academy of Sciences (NAS) released its review of the EPA draft toxicological review.⁶ The SAB considered this document prior to making its final recommendation on formaldehyde. While the NAS document included many criticisms of the EPA toxicological review of formaldehyde, it supported the conclusions of EPA and others regarding formaldehyde and nasopharyngeal cancer, specifically that there is sufficient evidence of a causal association between formaldehyde and cancers of the nose, nasal cavity, and nasopharynx.

The SAB confirmed its recommendation to designate formaldehyde as a Higher Hazard Substance, based primarily on the findings of IARC, EPA and the NAS review panel regarding nasopharyngeal cancer in humans. The SAB vote was 5:1:1 (for:abstain:against). For more information on the data considered by the SAB in developing its recommendation, see Appendix A.

Acute toxicity

- Acute exposure to formaldehyde causes throat, nose, eye and skin irritation. People with asthma may be more sensitive to the effects of inhaled formaldehyde.⁷
- Formaldehyde causes narrowing of the bronchi resulting in coughing, wheezing, chest pains and bronchitis⁸ when inhaled. At high levels, formaldehyde can cause fluid build-up in the lungs and can result in death.⁹ The threshold level for development of acute symptoms due to inhalation is 800 ppb. However, sensitized individuals may experience symptoms at levels around 100 ppb.¹⁰
- Severe burns can result from skin contact and some formaldehyde may pass through the skin. In sensitized persons, contact dermatitis may develop at very low exposure levels.¹¹

Chronic toxicity

- In 2006, IARC changed the formaldehyde classification from Group 2A (probable human carcinogen) to Group 1 (carcinogenic to humans).¹² This classification was based on “sufficient evidence of nasopharyngeal cancer in humans, strong but not sufficient evidence of leukemia in humans, and limited evidence of sinonasal cancer in humans.”¹³ In 2009, IARC reaffirmed the Group 1 classification and also concluded that there was sufficient evidence of leukemia in humans.¹⁴
- The National Toxicology Program (NTP) has determined that formaldehyde may reasonably be anticipated to cause cancer.¹⁵ Formaldehyde is also considered to be a probable human carcinogen by the U.S. Environmental Protection Agency (EPA) (Group B1).¹⁶ NTP¹⁷ and EPA¹⁸ are currently carrying out reassessments of formaldehyde, taking into account the 2006 IARC reclassification.

- Studies conducted by the National Cancer Institute (NCI) found an increased risk of lung and nasopharyngeal cancers and leukemia among funeral industry workers, such as embalmers in mortuaries, from occupational exposure to formaldehyde.¹⁹
- Formaldehyde exposure has been associated with reproductive effects such as spontaneous abortions, congenital malformations, low birth weights, infertility and endometriosis.²⁰
- The Association of Occupational and Environmental Clinics (AOEC) lists formaldehyde as an occupational asthmagen. The Collaborative on Health and the Environment (CHE)²¹ states that there is good evidence for an association between formaldehyde and the onset of allergic asthma. Other studies have also shown a link between asthma and formaldehyde exposure from indoor air. A study with comprehensive exposure assessment of formaldehyde found an increased risk of childhood asthma with increased exposure.²² Another study found a relationship between severe allergic sensitization, particularly among children with respiratory symptoms, and increased formaldehyde exposure.²³
- Long term exposure may result in sensitization and increased risk of contact dermatitis and asthma attacks.

2. Number of facilities affected

Formaldehyde is primarily used in the manufacture of wood adhesives applied to plywood, particleboard and other manufactured wood products, and in formaldehyde-based resins. The wood adhesive industry is the largest consumer of formaldehyde, accounting for about 64% of total formaldehyde use in the United States in 2003.²⁴ Other significant uses of formaldehyde include the manufacture of other chemicals, plastics and coatings, permanent press fabric treatments and fertilizers.

a. Historical data on sectors using formaldehyde in Massachusetts

Formaldehyde is not intentionally manufactured from feedstock chemicals in Massachusetts. However, formaldehyde and substances derived from it are extensively processed and used in the manufacture of other materials and products. Historically, formaldehyde has been reported under TURA by the sectors listed below.

Industrial sectors reporting formaldehyde use under TURA	
Sector SIC Code	Description
2269	Finishing plants
2295	Coated fabrics, not rubberized
2621	Paper mills
2672	Coated and laminated paper
2821	Plastics materials and resins
2869	Industrial organic chemicals
2899	Chemical preparations
3131	Footwear cut stock
3291	Abrasive products
3672	Printed circuit boards

3679	Electronic components
3769	Space vehicle parts and equipments
4911	Electric services
4925	Gas production and/or distribution
5122	Drugs, proprietaries and sundries
5169	Chemicals and allied products

The number of facilities that have historically reported the various applications of formaldehyde under TURA decreased between 1990 and 2008.

- For example, in 1990, five facilities reported using formaldehyde for electroless copper processes in printed wiring boards (PWB). This number decreased to three in 1998 and in 2007 only one facility reported using formaldehyde in PWB.²⁵
- The number of facilities reporting formaldehyde use in the Leather Products and Organic Chemicals sectors dropped to zero by 1998.

The number of facilities reporting formaldehyde use in resins, embalming chemicals, chemical distribution, fabrics and paper coating remained relatively consistent over the reporting years. A significant note is that some of the paper and fabric facilities use resins to coat the paper or fabrics, making resins one of the most significant uses in Massachusetts. In addition, 2008 data show one resin manufacturer that previously requested, and was granted, trade secret status for its reported data. This manufacturer uses 10 times more formaldehyde than the other users combined.

TURA filers using formaldehyde in 1990, 1998 and 2008, categorized by use type			
Use	Number of Facilities		
	1990	1998	2008
Chemical distribution	1	1	1
Electroless copper	5	3	1
Embalming chemicals	1	1	1
Paper	4	4	2
Resins	1	1	3
Leather	1	0	0
Textiles	1	1	0
Organic chemicals	2	0	0
Fuel combustion	0	2	1
Total Filers	16	13	9

b. Current data on formaldehyde use in Massachusetts

During 2008, nine TURA filers reported use of formaldehyde. Three filers were in the resin manufacturing sector, and two were in the custom papers sector. There was one company each from the gas production and/or distribution sector, chemical distribution, electroless copper, and the embalming chemicals sector. Of particular note, 2008 data show a resin manufacturer that previously requested and received trade secret status.

c. Estimated number of companies that would be affected by a lower reporting threshold

To estimate the potential number of facilities that would be affected by the lowered reporting threshold, the TURA program used information provided by past and present TURA filers, as well as additional information from the sources listed below:

- EPA's TIER II database and MassDEP's Hazardous Air Pollutants database demonstrate few potential new filers.²⁶
- OTA staff estimate that the facilities very likely to still be processing or using formaldehyde are in sectors 2295 (coated fabrics), 2672 (coated and laminated paper), and 2899 (chemicals and resins manufacturing).
- Universities, hospitals and municipalities are more prevalent known users of formaldehyde. However, they are not subject to TURA requirements.

Based on the information above, TURA program staff members estimate that a small number of facilities (fewer than 5 each) might be expected to file in the sectors of coated fabrics, custom papers and chemicals manufacturing. One or two filers in other sectors with historical use of formaldehyde may also be affected by the lowered reporting threshold. In total, the TURA program estimates that between 10 and 25 facilities would be required to file under TURA.

3. Opportunities for New Filers

The feasibility of adopting formaldehyde alternatives varies depending on the application. In addition to consulting written sources, in July 2010 TURA program staff members met with representatives of several facilities that use formaldehyde to gather more specific use information and to learn what alternatives they had previously explored. This meeting was organized and facilitated by the Massachusetts Chemical and Technology Alliance (MCTA).

Below is a summary of trends in formaldehyde use among TURA filers and alternatives for some of the most frequent uses of formaldehyde.

a. Trends in formaldehyde use

Sixteen TURA filers reported formaldehyde use in 1990. By 2008, the most recent year for which data are available, this number had dropped to nine.

From 1990 to 2007, the TURA data show that total formaldehyde use and on-site releases decreased by 64% and 66% respectively. However, the use figure rose dramatically in 2008 due

to the inclusion of one facility that previously received trade secret status. This facility uses approximately 20 million pounds of formaldehyde annually. Thus, from 1990 to 2008, the data show formaldehyde use more than doubling, as shown in the table below. Without the inclusion of this large filer in previous years, it is difficult to make meaningful statements about trends in total formaldehyde use over time.

Massachusetts TURA Data: Formaldehyde Used and Released (On-Site) in 1990 and 2008*				
	Year		Change in lbs	% Change
	1990	2008		
Formaldehyde used (lbs) among TURA filers	9,184,923	22,536,216	+13,351,293	+145%
Formaldehyde released (on-site) (lbs)	180,126	28,066	-152,060	-84%
*Note: 2008 data show one resin manufacturer that previously requested, and was granted, trade secret status for its reported data. This manufacturer uses 10 times more formaldehyde than the other users combined.				

b. Opportunities to reduce formaldehyde use

Practical alternatives to formaldehyde uses are available for a variety of processes such as the manufacturing of resins, printed wiring boards and building materials. For other common uses of formaldehyde, there is potential for additional research and development of alternatives that may have less impact on human health and the environment. TURA filers thus have the opportunity to significantly reduce their use of formaldehyde.

(i) Alternatives for electroless copper process in printed wiring boards

Printed wiring boards (PWBs) are essential components of many electronic products which have applications in defense, communication and automotive manufacturing industries. Electroless copper process is the technology traditionally used by PWB manufacturers to make PWB through-holes conductive prior to electrolytic plating. The electroless copper process is a wet chemical process and it requires the use of hazardous materials, including formaldehyde, of concern to human health and the environment. It also consumes large amounts of water and energy. Most of the available alternative technologies for making holes conductive that have been identified by the EPA eliminate the use of formaldehyde, reduce water and energy use, and generate less waste. They include carbon-based, conductive polymer, graphite-based, non-formaldehyde electroless copper, and organic and tin palladium processes. According to an analysis by the EPA these alternative technologies perform as well or better than the traditional electroless copper process.²⁷

(ii) Options for reducing or eliminating formaldehyde in resins²⁸

Formaldehyde is frequently used in the manufacture of resins. Options for reducing formaldehyde use in this area include reformulating resins to use smaller amounts of formaldehyde; or switching to resins that do not contain formaldehyde. OTA staff members have

worked with facilities to reduce formaldehyde content in resins, and TURI has sponsored research on alternative resins that do not contain formaldehyde.

For example, epoxidized vegetable oils show promising application potential in the manufacture of particleboard. These include epoxidized linseed oil (ELO), epoxidized soybean oil (ESO), and epoxidized castor oil (ECO). In 2009, TURI sponsored a preliminary study by University of Massachusetts Lowell researchers, examining options for replacing conventional resins with these epoxidized vegetable oil resins. The study provided information on the physical properties of the alternative resins, but the study authors were not able to make a full viability comparison between the conventional and alternative resin types.²⁹ This is an area in which additional research would be appropriate.

One of the major uses of formaldehyde-containing resins is in building materials. Resin-based building panels and other building materials that do not require the use of formaldehyde-based resins are readily available. Some of these alternatives pose concerns related to occupational exposures during manufacture, while others are likely to be preferable from an occupational exposure perspective. Some examples are provided in the text box below.

Examples of alternatives for formaldehyde resin-based building materials

- One alternative for formaldehyde resin-based building panel is a hardwood veneer core plywood panel developed by Columbia Forest Products. The panel is made with PureBond core and laminated veneers. PureBond is produced with soy flour and a polyamide-epichlorohydrin (PAE) resin. IARC and EPA have identified epichlorohydrin as a probable human carcinogen, groups 2A³⁰ and B2³¹ respectively. Chronic exposure to epichlorohydrin in an occupational setting is also associated with high levels of respiratory tract diseases and hematological effects. According to the manufacturer and the EPA, there are no emissions and no residual epichlorohydrin in PAE production because it is irreversibly altered in the polymer matrix.
- Other alternative panels include Homasote's recycled paper panel board and Viroc's wood fiber-Portland Cement panel. These may be substituted for plywood or oriented strand board (OSB) in building sheathing, roof decking or floor decking.
- Yet another alternative panel is JER EnviroTech's plastic-wood panel, which may have applications in particleboards and structural use panels.
- In addition, soybean protein modified with sodium dodecyl sulfate (SDS) can be used as an alternative resin for wood fiber medium density fiberboard (MDF) preparation. Soybean protein resins have been traditionally used for wood board preparation such as cardboard, oriented strand board, wheat straw particleboard, and low density particleboard from wheat straw and corn pith.³²

(iii) Alternatives for paper coating³³

Formaldehyde is used as a wet strength resin in paper coating. In Massachusetts, formaldehyde-containing paper coating resins are predominantly used in architectural finish applications. Substitute paper coating resins which contain no added formaldehyde include resins made from polyamide, polyamine, epichlorohydrin, and acrylic. Some of these alternatives also pose health concerns. Epichlorohydrin is identified as a carcinogen by IARC and EPA, and has been shown to cause respiratory tract diseases and hematological effects in exposed workers. Polyurethane resin, such as polyurethane dispersions, could also be used as coating materials. Polyurethane

dispersions are known to have good bonding strength and abrasion resistance, as well as heat and temperature stability. Again, paper coating applications are a potentially important area for additional research to evaluate alternatives to formaldehyde-based resins.

(iv) Alternatives for permanent press fabric treatment

Substances shown to have the potential of replacing formaldehyde-based agents in permanent press fabric treatment include phosphinocarboxylic acid.³⁴ Also, treating fabrics with maleic acid and sodium hypophosphite may be an alternative method of achieving permanently pressed fabrics without the use of formaldehyde-based substances.³⁵

Other formaldehyde uses of interest³⁶

In addition to industrial uses, it is worth considering some uses of formaldehyde that are not currently reportable under TURA, but may be significant sources of exposure. These include formaldehyde use in barbering/cosmetology; specimen preservation in laboratories; and human body preservation in mortuaries.

Sanitary storage in barbering/cosmetology³⁷

The Massachusetts Board of Cosmetology mandates that cosmetic salons use “dry sanitizer” in drawers where tools such as hair brushes are kept.³⁸ Dry sanitizer is generally understood to refer to steri-dry, a paraformaldehyde product. The Board also lists both steri-dry and formalin solution explicitly as an option for sanitizing instruments after use.³⁹ These requirements are at odds with nationally accepted standards.

Steri-dry consists of a perforated plastic container containing paraformaldehyde, which slowly emits formaldehyde gas as it de-polymerizes. Use of paraformaldehyde as a dry sanitizer is a potentially significant source of formaldehyde exposure in salons and cosmetology training schools, including vocational schools.

Contrary to the Massachusetts Board of Cosmetology, the National Interstate Council of State Boards of Cosmetology (NIC) does not recommend the use of paraformaldehyde or of formalin. The NIC recommends an alternate procedure of proper cleaning, wet disinfection with EPA-registered disinfectants, drying and storage of tools in covered containers to assure isolation from contaminants.⁴⁰ *Milady's Standard Cosmetology*, the authoritative source of cosmetology procedures and the key reference text upon which the NIC relies, includes explicit warnings against the use of formaldehyde-containing products.⁴¹ According to information provided to TURI by NIC in 2006, Massachusetts is the only state that requires the use of formaldehyde-based dry sanitizer.

The Massachusetts Healthy Nail Salon Workgroup has provided a number of recommendations to the state Board of Cosmetology on ways to modify salon regulations to create healthier and safer workplaces for nail salon workers, as well as for the public and salon neighbors.⁴² In June 2008, the Workgroup submitted a list of recommendations to the board, including a

recommendation to eliminate the use of formaldehyde-based dry sanitizers. The Board of Cosmetology has not yet taken action on these recommendations.

Embalming/preserving of educational specimens

Formalin solution (aqueous solution of formaldehyde) are used to treat and store educational specimens to prevent the natural decay of tissues. Formaldehyde kills bacteria that cause tissue decomposition and polymerizes the tissue to help maintain its texture, structure and color.

Students, laboratory instructors, technicians and others can be exposed to formaldehyde in the course of their work with these specimens. Usually, smaller animals are dissected within two weeks, whereas larger animals such as cats may be used by students for about two semesters or more. Consequently, students, laboratory instructors and technicians' exposure time to formaldehyde may be significantly increased.

Alternatives for formaldehyde use in tissue preservation that were identified and considered in TURI's 2006 *Five Chemicals Alternatives Assessment Study* include three specimen alternatives and a virtual video dissection.⁴³

Embalming/preserving human bodies in mortuaries⁴⁴

Mortuaries use formaldehyde for fixing and preserving human bodies for funeral services. Although mortuaries are a sector subject to TURA, industry sources indicate that mortuaries are unlikely to meet the 1,000 lb/year threshold. However, one of the facilities currently reporting formaldehyde use under TURA is a supplier of formaldehyde solutions to mortuaries. It may be appropriate for the TURA program to work with this manufacturer and engage in outreach to mortuaries as part of a broader effort to reduce occupational exposures to formaldehyde.

Embalmers at mortuaries are exposed to formaldehyde during the course of their work. The degree of exposure to formaldehyde depends in part on whether the body being embalmed is intact or has been autopsied. Risk of exposure is greater when embalming autopsied bodies due to the fact that a relatively longer time and higher concentration of formaldehyde is required to embalm autopsied bodies.⁴⁵

Potential alternatives that are available for substitution or reduction of formaldehyde use in embalming include glutaraldehyde-based and phenol-based substances.⁴⁶ However, these alternatives are not necessarily safer for human health. For example, glutaraldehyde exposure has been associated with eye, skin, and respiratory irritation; system, dermatitis, skin sensitization, and asthma.⁴⁷ The Massachusetts manufacturer of embalming chemicals also has a new formaldehyde-free formulation available. They report that it is not as effective as the formaldehyde based products, but that it is appropriate for situations where only temporary preservation is needed.

Mortuaries can also eliminate or reduce their use of formaldehyde through the use of alternative technologies or practices for preserving human bodies. Available alternatives include changing burial procedures, disinfecting the body surface with an alcohol solution, using refrigerated

storage, and carrying out a closed casket funeral service for bodies with no infectious diseases. A closed casket funeral service would require no embalming if the human body is well disinfected on the surface. Refrigerated storage is appropriate if the body is to be kept for a long period of time.

Formaldehyde is also used in hospitals for tissue preservation and fixation. In a study, one hospital which used formaldehyde in its histopathology laboratory replaced the chemical with another chemical containing glyoxal, a less toxic aldehyde. According to the study, this alternative chemical was a direct chemical substitute and required minimal work reorganization, implementation time and initial costs. Technical feasibility analysis showed that the alternative chemical performed as well as formaldehyde in preparation of most, but not all, tissues. However, the study concluded that the alternative lacked sufficient toxicological information.⁴⁸ Again, this is an area in which additional research would be appropriate.

c. Implementation: Opportunities and challenges

The availability of some alternatives in custom paper, coated paper and resins, as well as other common uses of formaldehyde, provides an opportunity for facilities to reduce or eliminate their use of formaldehyde. The Office of Technical Assistance and the Institute are in a good position to assist facilities make the switch to safer and efficient alternatives. In addition, there are important opportunities for outreach to facilities that are not covered under TURA, but that do use formaldehyde in ways that are likely to lead to significant worker exposures.

There are also important challenges. Formaldehyde is a basic building block chemical for manufacturing of many different chemicals and products. It is used in a wide variety of applications in many different production processes. Therefore, there is no single alternative that will be appropriate for all uses of formaldehyde. There is a need for process-specific problem solving to identify formaldehyde alternatives in many applications. In addition, for many applications there are no safer, equally effective alternatives currently available.

Helping facilities to shift to alternative resins is a particularly important area for focus going forward. In this effort, there may be important opportunities to use the techniques and approaches of green chemistry and of biomimicry, such as identifying alternative ways to manufacture resins using renewable plant-based materials.

4. Regulatory Context

Formaldehyde is subject to a variety of federal and state regulations as well as international regulations as a result of its toxicity. For a glossary of regulations referred to in this section, see Appendix B.

U.S. federal regulations on formaldehyde

EPCRA	<ul style="list-style-type: none"> • Subject to reporting under TRI Sec. 313⁴⁹ • 500 lb reporting threshold under TPQ Sec. 302 and 100 lb reporting threshold under Sec. 304⁵⁰
CAA	<ul style="list-style-type: none"> • A listed Hazardous Air Pollutant⁵¹
RCRA	<ul style="list-style-type: none"> • Classified as a hazardous waste⁵²
CERCLA	<ul style="list-style-type: none"> • A listed priority hazardous substance⁵³
OSHA (TWA)	<ul style="list-style-type: none"> • PEL: 0.75 ppm⁵⁴
OSHA STEL	<ul style="list-style-type: none"> • 2 ppm
OSHA IDLH	<ul style="list-style-type: none"> • 100 ppm⁵⁵
NIOSH (TWA)	<ul style="list-style-type: none"> • REL: 0.016 ppm⁵⁶
NIOSH IDLH	<ul style="list-style-type: none"> • 20 ppm
ACGIH (TWA)	<ul style="list-style-type: none"> • TLV: 0.3 ppm⁵⁷
SDWA	<ul style="list-style-type: none"> • Contaminant Candidate List 3 (CCL 3)⁵⁸
FIFRA	<ul style="list-style-type: none"> • Registered pesticide⁵⁹

Massachusetts regulations on formaldehyde

Massachusetts: Workplace Regulation	<ul style="list-style-type: none"> • Subject to Right-to-Know standards⁶⁰
Massachusetts: Public & Environmental Health	<ul style="list-style-type: none"> • 24-hour threshold exposure limit is 0.27 ppb; annual allowable exposure limit: 0.06 ppb⁶¹

a. Other relevant state regulations of formaldehyde

Some states have gone beyond federal statutes with respect to formaldehyde regulation

- Formaldehyde is regulated as a carcinogen under the state of California's Safe Drinking Water and Toxics Act of 1986 (Proposition 65).⁶² Under this law, companies must provide notification when a product or workplace exposes an individual to a chemical that causes cancer and/or reproductive toxicity. Proposition 65 requires that the Governor revise and republish a list of chemicals that are known to the state to cause cancer or reproductive toxicity at least once every year. Formaldehyde is also a tier 2 Toxic Air Contaminant under the state's Children's Environmental Health Protection Act.⁶³
- California Air Resources Board's Air Toxics Control Measure (ATCM) set standards for formaldehyde emissions from composite wood products, including hardwood plywood, particle board and medium density fiberboard (MDF). Manufacturers of hardwood plywood, particleboard, and MDF that manufacture, sell, offer for sale, or supply these products for use in California are subject to the requirements of the ATCM.⁶⁴ The federal Formaldehyde Standards for Composite Wood Products Act, signed into law in July 2010, makes the California standards applicable nationwide.⁶⁵

- Formaldehyde is reportable under the New Jersey Worker and Community Right to Know Act.⁶⁶ The act mandates businesses with assigned NAICS codes that are listed in the NJ Worker and Community Right to Know (CRTK) regulation to submit environmental surveys listing any environmental hazardous substances present at their facilities in quantities that exceed 500 lb, unless the substance is also listed on EPCRA Section 302 list of extremely hazardous substances with a lower reporting threshold.⁶⁷ The surveys must include the total amount of the hazardous substance used and emitted, as well as facilities' pollution prevention activities.
- Maine's Department of Environmental Protection has listed formaldehyde as a hazardous air pollutant with a reporting threshold of 1,000 lb of manufactured, processed or used of the chemical. The state also mandates that formaldehyde emissions for all fuel or combustion equipments must be reported irrespective of whether the threshold level is reached or exceeded.⁶⁸ The state agency has also listed the chemical as a "chemical of high concern" under its Toxic Chemicals in Children's Products law.⁶⁹
- The state of Rhode Island's Department of Environmental Management also lists formaldehyde as a toxic air contaminant and has set maximum hourly, 24-hour and yearly ambient air concentration levels from stationary sources at or beyond facilities property lines.⁷⁰
- Formaldehyde is listed on the draft reporting list of chemicals of high concern to children under the state of Washington Children's Safe Products Act (CSPA).⁷¹ This law requires manufacturers of children's products containing any listed chemical to notify the Department of Ecology after final rules to implement the CSPA are in place.

b. International regulations on formaldehyde

- Formaldehyde is a chemical on the SIN list of Substances of Very High Concern (SVHC).⁷² The SIN list is a compilation of hazardous chemicals created by an advocacy organization. The list is based on the standards established by the new European Union chemical regulation, REACH and it seeks to provide a tool that companies can use to substitute hazardous chemicals with safer alternatives while at the same time promoting change in legislations.
- In the European Union, formaldehyde is listed as a dangerous substance and is subject to Annex VI classification, labeling and packaging (CLP) regulation by the European Chemicals Agency (ECHA).⁷³ ECHA manages the registration, evaluation, authorization and restriction processes for chemical substances to ensure consistency across the European Union.
- Formaldehyde is regulated by the Swedish Chemical Agency (KEMI) under the Chemical Products and Biotechnical Organisms Regulations (KIFS 2008:2), Chapter 5: sections 19, 20 and 24.⁷⁴ The regulation sets an emission limit value for formaldehyde in wood-based boards and prohibits marketing and sale of boards not meeting the required standards.
- In Japan, formaldehyde in building materials are subject to emission control under the Building Standard Law on Sick House Issues.⁷⁵

Important non-regulatory initiatives on formaldehyde

- Leadership in Energy and Environmental Design (LEED): requires no added urea-formaldehyde resins in composite wood and agrifiber products that are used in building.⁷⁶ LEED is an internationally recognized green building certification system developed by the U.S. Green Building Council. It provides third-party certification on buildings or communities designed and built using strategy aimed at improving performance in the areas of energy savings, water efficiency, CO₂ emissions reduction, improved indoor environmental quality, and stewardship of resources and sensitivity to their impacts.

5. Implications for the TURA Program

The TURA program has a variety of resources to help companies reduce or eliminate their use of formaldehyde.⁷⁷ In particular, OTA has experience working with companies to reduce the amount of formaldehyde in resin formulations; and TURI has conducted extensive research on formaldehyde alternatives for a number of applications.

However, the wide range of applications of formaldehyde in production may pose some challenges for the program, particularly in identifying feasible alternatives for the manufacture of resins. This is an area in which it would be appropriate for the TURA program to sponsor additional research.

In addition to uses of formaldehyde by TURA filers, there may be some important opportunities for the TURA Administrative Council, in its coordinating role, to help address formaldehyde exposures in small businesses. For example, the council can identify appropriate avenues for working with the Massachusetts Board of Cosmetology its requirements regarding formaldehyde-based dry sanitizer.

Facilities that will begin reporting formaldehyde use under TURA based on a lower reporting threshold will be required to prepare toxics use reports and biennial toxics use reduction plans. Facilities will also pay a base fee which is determined by facility size, plus a per-chemical fee of \$1,100.

Facilities that will file for formaldehyde under the lower reporting threshold are likely to be small-sized. The base fee a small-sized facility with 10 to 50 employees is \$1,850. For a facility with 50 to 100 employees, the base fee is \$2,775. If all the filers brought in based on the lower reporting threshold are new facilities that are not already in the program, it will cost a facility with 10 to 50 employees \$2,950, whereas a facility with 50 to 100 employees will pay \$3,875. As a result, the total cost in fees to new TURA filers (or revenue to the program) could be between \$29,500 and \$73,750 (for facilities with 10 to 50 employees) and between \$38,750 and \$96,875 (for facilities with 50 to 100 employees), assuming that 10 to 25 facilities will be required to file.

On the other hand, if the filers brought in based on the lower reporting threshold already file under TURA, then the only additional cost to those facilities will be the per-chemical fee for use of formaldehyde. In this case, the total cost to filers could be \$11,000 to \$27,500.

6. Paraformaldehyde

Paraformaldehyde (CAS # 30525-89-4) is a polymerized solid form of formaldehyde. As paraformaldehyde depolymerizes, it emits formaldehyde in the form of a gas.⁷⁸ Paraformaldehyde is frequently used in industry as a source of formaldehyde gas. Because paraformaldehyde has a polymerized structure distinct from formaldehyde and because it is on the TURA chemical list, it is reported separately under TURA.

At room temperature and pressure, paraformaldehyde slowly de-polymerizes, releasing molecules of formaldehyde from the solid crystalline polymer to the gas phase. There is also a small percentage of free formaldehyde that off-gasses over time. The rate of formaldehyde release increases with increasing temperature and humidity.

After reviewing the preliminary Higher Hazard Substance policy analysis for formaldehyde, the Advisory Committee recommended that the program consider paraformaldehyde along with formaldehyde. Paraformaldehyde is a listed substance under TURA but had not been considered by the Science Advisory Board for possible designation as a Higher Hazard Substance. Responding to this request, the Science Advisory Board reviewed the scientific information about paraformaldehyde and its toxicity. The SAB concluded that paraformaldehyde's hazards are greatest when it forms formaldehyde and that when formaldehyde is formed it will be reportable as such. For this reason, the SAB recommended that paraformaldehyde remain "uncategorized," that is, did not recommend it for Higher Hazard Substance status.

The following sections provide information on paraformaldehyde toxicity, use and policy considerations.

Characterizing the toxicity of paraformaldehyde. It is difficult to draw a distinction between the health effects of paraformaldehyde and those of formaldehyde. Many published studies of the health effects of formaldehyde actually use paraformaldehyde as the exposure source. (For example, a researcher studying inhalation effects of formaldehyde may choose paraformaldehyde as the exposure source.) Furthermore, many studies of the health effects of paraformaldehyde are actually measuring the effects of formaldehyde exposure. For example, all inhalation studies of paraformaldehyde are actually studies of formaldehyde.

In some cases, the toxicity of paraformaldehyde products is characterized based on the percentage of free formaldehyde contained within them. In general, paraformaldehyde products include a small percentage of water as well as a small percentage of free, nonpolymerized formaldehyde. The European Inventory of Existing Commercial Chemical Substances (EINECS) provides risk phrases (R-phrases) for formaldehyde that depend on the concentration at which formaldehyde is present in the substance being evaluated. Thus, one option to describe the toxicity of paraformaldehyde is to apply the risk phrases that apply to the percentage of free formaldehyde that is present in it. A drawback to this approach is that this does not take account of the additional formaldehyde that is generated by de-polymerization. Some Materials Safety Data Sheets for paraformaldehyde provide both (a) the EINECS R-phrases for the relevant concentrations, and (b) the R-phrases for formaldehyde gas.⁷⁹

Some systems do not list paraformaldehyde separately for purposes of toxicity categorization. Others do list paraformaldehyde separately. For example, the Registry of Toxic Effects of Chemical Substances (RTECS) maintained by NIOSH lists both formaldehyde and paraformaldehyde as suspected neurotoxicants⁸⁰, and HAZMAP, an occupational health and toxicology database maintained by the National Library of Medicine, lists both formaldehyde and paraformaldehyde as suspected skin or sense organ toxicants and suspected immunotoxicants.

Paraformaldehyde use in Massachusetts: TURA filers. Three facilities have reported paraformaldehyde use under TURA.

- One facility in the coated fabrics sector has reported paraformaldehyde use every year from 1993 to 2008.
- One facility in the industrial organic chemicals sector reported paraformaldehyde use from 1993 to 1997, and another facility in the same sector reported paraformaldehyde use in 2004 only.
- Paraformaldehyde use among TURA filers has decreased by 51% from 1993 to 2007 and paraformaldehyde releases have decreased by 100%.

It is important to note that some TURA filers have made errors in reporting information on paraformaldehyde and formaldehyde use. For example, one facility that uses paraformaldehyde to generate formaldehyde, in order to synthesize a formaldehyde phenol resin, has not reported the formaldehyde as an intermediate. Rather, the facility has reported the formaldehyde that was generated as byproduct or was present in the final resin as residual free formaldehyde. In the future, it will be important to provide additional guidance to TURA filers to clarify reporting requirements.

Massachusetts TURA Data: Paraformaldehyde Used and Released (On-Site) in 1993 and 2008				
	Year		Change in lbs	% Change
	1993	2008		
Para-formaldehyde used (lbs) among TURA filers	1,174,567	577,595	-596,972	-51%
Para-formaldehyde released (on-site) (lbs)	70	0	-70	-100%

Paraformaldehyde use in Massachusetts: Smaller uses. As noted above, Massachusetts regulations require hair salons to use paraformaldehyde as a means to generate gaseous formaldehyde in storage drawers. This is a low-volume use that would not be captured under TURA even if paraformaldehyde were subject to a 1,000 lb reporting threshold. However, it is a potentially important source of preventable formaldehyde exposure and provides an opportunity for coordination of relevant agency activities by the Administrative Council.

Paraformaldehyde is also used as a preservative in some mortuary embalming products, including embalming powders and some autopsy and hardening compounds.

Classification and regulation of paraformaldehyde. Some systems of classification and regulation treat formaldehyde and paraformaldehyde as different forms of a single chemical, while other systems treat them as two distinct chemicals.

Formaldehyde and paraformaldehyde have distinct CAS identification numbers. In contrast, the European Inventory of Existing Commercial Chemical Substances, or EINECS, does not have an identification number for paraformaldehyde, because it does not include polymers.

The European Union’s Cosmetics Directive regulates formaldehyde and paraformaldehyde together, along with a group of chemicals categorized as “formaldehyde releasers.”⁸¹ Cosmetics containing any of these substances are required to be labeled as “contains formaldehyde.”

As shown in the following table, some U.S. federal regulations apply to paraformaldehyde specifically, whereas others do not mention it separately from formaldehyde.

EPCRA	<ul style="list-style-type: none"> • Not reportable under TRI.⁸²
CAA	<ul style="list-style-type: none"> • Not reportable (Not listed as a Hazardous Air Pollutant.)⁸³
CWA	<ul style="list-style-type: none"> • Designated as a hazardous substance under section 311(b)(2)(A) of the Federal Water Pollution Control Act and further regulated by the Clean Water Act Amendments of 1977 and 1978.⁸⁴
RCRA	<ul style="list-style-type: none"> • No RCRA code indicated on List of Lists.⁸⁵
CERCLA	<ul style="list-style-type: none"> • Paraformaldehyde is a CERCLA hazardous substance that is subject to reporting if released into the environment in amounts equal to or exceeding 1000 lbs. At this threshold level, it is also subject to state and local reporting requirements under section 304 of EPCRA.⁸⁶
OSHA (TWA)	<ul style="list-style-type: none"> • PEL: Not listed.⁸⁷
OSHA STEL	<ul style="list-style-type: none"> • Not listed.⁸⁸
OSHA IDLH	<ul style="list-style-type: none"> • Not listed.⁸⁹
NIOSH (TWA)	<ul style="list-style-type: none"> • REL: Not listed.⁹⁰
NIOSH IDLH	<ul style="list-style-type: none"> • Not listed.⁹¹
ACGIH (TWA)	<ul style="list-style-type: none"> • TLV: Not listed.⁹²
SDWA	<ul style="list-style-type: none"> • Not listed.⁹³
FIFRA	<ul style="list-style-type: none"> • Paraformaldehyde is a registered pesticide.⁹⁴ EPA completed its reregistration eligibility decision for formaldehyde and paraformaldehyde in June 2008.⁹⁵

Policy options for paraformaldehyde. TURI considered several possible policy options for paraformaldehyde: designate paraformaldehyde as a higher hazard substance; create a category for formaldehyde and paraformaldehyde; or make no change in the status of paraformaldehyde. In TURI’s opinion, each of these options could be justified from a policy perspective. The considerations related to each of these options are discussed in more detail in Appendix C. TURI’s final recommendation is to make no change in the status of paraformaldehyde.

This recommendation is based on the understanding that most or all paraformaldehyde users that would be affected by this designation will be covered by the higher hazard designation for formaldehyde itself.

Members of the Advisory Committee posed a number of questions about this recommendation. At least one industry representative and one advocacy representative favored the option of creating a category. These committee members argued that the benefits of clearer, more precautionary information provided to industry outweighed the drawback of less detail provided to the TURA program in annual data reports. Other committee members suggested that it would be most logical to designate both formaldehyde and paraformaldehyde as higher hazard substances. Others noted that designating paraformaldehyde as a HHS would not fundamentally change TUR activities or the program's message. From TURI's perspective, these considerations were counterbalanced by other factors, including the fact that the HHS designation for formaldehyde is expected to capture all of the facilities that would be captured by designating paraformaldehyde as a HHS.

In summary, while a reasonable case can be made for other approaches, TURI believes that based on current information, making no change to the status of paraformaldehyde is the most practical option for the program at this time.

7. Summary

Formaldehyde is recognized as a priority chemical in many jurisdictions, and due to its toxicity it is subject to a variety of state, national and international regulations. Designating formaldehyde as a higher hazard substance will enable the TURA program to work collaboratively with facilities, through TUR planning and identifying safer alternatives, to reduce the use of formaldehyde. The fact that formaldehyde is used in a wide variety of applications may pose some challenges in identifying safer alternatives; there is scope for additional research and development in developing alternatives. Both the Office of Technical Assistance and the Toxics Use Reduction Institute are equipped to assist facilities in identifying safer alternatives or processes, and to help support research on applications in which alternatives are not readily available. Regarding paraformaldehyde, the Institute recommends making no change in its status.

Appendix A: Data the SAB Considered for Formaldehyde

The following data were considered the first time the SAB reviewed the science on formaldehyde, in 1998-1999. This information was the basis for the SAB's original categorization of formaldehyde as a More Hazardous Substance, and was reviewed again when the SAB recommended higher hazard status designation for formaldehyde, in 2007. Other information considered subsequently is discussed in the text.

International Agency for Research on Cancer (IARC)	Group 2A (probable human carcinogen), upgraded to Group 1 (carcinogenic to humans) in 2006*
PBT Profiler:	
Half life in water	15 days
Half life in soil	30 days
Half life in sediment	140 days
Half life in air	1.7 days
Bioconcentration factor	3.2
ChV	2.7
LD50 (mouse)	385 mg/kg
Reference Dose (RfD)	.2mg/kg/day
ATSDR Minimum Risk Level: acute inhalation	.04 ppm
ATSDR Minimum Risk Level: chronic inhalation	.008 ppm
ATSDR Minimum Risk Level: chronic oral	0.2 mg/kg/day
Flash Point	181.4 closed cup
*Group 2A (probable human carcinogen) was IARC's designation at the time the SAB first classified formaldehyde as a More Hazardous Substance under TURA. In 2006, IARC revised the classification to Group 1 (carcinogenic to humans), based on "sufficient evidence of nasopharyngeal cancer in humans, strong but not sufficient evidence of leukemia in humans, and limited evidence of sinonasal cancer in humans." IARC reaffirmed the Group 1 classification in 2009, and also concluded at that time that there was sufficient evidence of leukemia in humans. (National Academy of Sciences, "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," April 2011).	

History of SAB deliberations related to the HHS designation of formaldehyde:

The SAB first examined the science on formaldehyde as part of its original chemical categorization process. Based on the science available at that time, the SAB categorized formaldehyde as a More Hazardous Chemical in 1999. In 2007, as the TURA program began implementation of its new authorities under the 2006 amendments to the Act, the SAB recommended formaldehyde as one of the first ten substances to be considered for Higher Hazard Substance designation.

TURI presented a recommendation to the Administrative Council to move forward with this designation in 2010. At that time, the Administrative Council requested that the SAB examine the new data on formaldehyde that had been generated in the interim.

Key developments in the science included the following:

- IARC changed the formaldehyde classification from Group 2A (probable human carcinogen) to Group 1 (carcinogenic to humans) in 2006. This classification was based on “sufficient evidence of nasopharyngeal cancer in humans, strong but not sufficient evidence of leukemia in humans, and limited evidence of sinonasal cancer in humans.”⁹⁶
- IARC reaffirmed the Group 1 classification in 2009, and also concluded at that time that there was sufficient evidence of leukemia in humans.⁹⁷
- In 2010, EPA released its draft health assessment for formaldehyde for EPA’s Integrated Risk Information System (IRIS).⁹⁸ This assessment, which EPA originally began in 1998, included the development of reference concentrations (RfCs) for noncancer effects and a carcinogenicity assessment, among other outcomes.
- At EPA’s request, the National Research Council (NRC) within the National Academy of Sciences (NAS) conducted an independent review of EPA’s assessment. The NAS review was completed in April 2011.

In its review of the science on formaldehyde, the SAB reviewed the findings of the NAS review. The SAB also received input from a member of the NAS review panel, as well as from industry experts. Based on this review, the SAB reaffirmed its original recommendation to designate formaldehyde as a Higher Hazard Substance.

Data the SAB considered for Paraformaldehyde

International Agency for Research on Cancer (IARC)	Not found
PBT Profiler:	
Half life in water	8.7 days
Half life in soil	17 days
Half life in sediment	78 days
Half life in air	17 days
Bioconcentration factor	3.2
ChV	590 mg/l
LD50 (mouse)	800 mg/kg (oral rat)

Reference Dose (RfD)	Not found
ATSDR Minimum Risk Level: acute inhalation	Not found
ATSDR Minimum Risk Level: chronic inhalation	Not found
ATSDR Minimum Risk Level: chronic oral	Not found
Flash Point	70C CC

Appendix B: Glossary of Regulatory Terms & Acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
CAA	Clean Air Act
CWA	Clean Water Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
EPCRA	Emergency Planning and Community Right-to-Know Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
IDLH	Immediately Dangerous to Life or Health
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
RCRA	Resource Conservation and Recovery Act
RQ	Releases of Reportable Quantities
RTECS	Registry of Toxic Effects of Chemical Substances
SDWA	Safe Drinking Water Act
STEL	Short Term Exposure Limit
TPQ	Threshold Planning Quantity
TRI	Toxic Release Inventory
TWA-PEL	Time Weighted Average – Permissible Exposure Limit
TWA-REL	Time Weighted Average – Recommended Exposure Limit
TWA-TLV	Time Weighted Average – Threshold Limit Value

Appendix C: Policy Considerations Related to Paraformaldehyde

Policy options for paraformaldehyde. TURI considered several possible policy options for paraformaldehyde: designate paraformaldehyde as a higher hazard substance; create a category for formaldehyde and paraformaldehyde; or make no change in the status of paraformaldehyde. In TURI's opinion, each of these options could be justified from a policy perspective. TURI's final recommendation is to make no change in the status of paraformaldehyde.

1. Designate paraformaldehyde as a higher hazard substance:

- This approach would potentially extend the reach of the TURA program to additional users.
- On the other hand, it is likely that any user brought in by a lower threshold for paraformaldehyde would already be brought into the program through the lower threshold for formaldehyde.
 - A potential exception would be facilities manufacturing deodorizers/sanitizers, because the formaldehyde generation in this case would occur after the product has left the facility. However, the TURA program is not aware of any Massachusetts facilities currently operating in this sector.
 - Another potential exception would be facilities that manufacture embalming products, such as embalming powders. The TURA program is aware of one such facility in Massachusetts; this facility currently files for formaldehyde use under TURA.

2. Create a category for formaldehyde and paraformaldehyde:

- Creating a category would reduce ambiguity in reporting. In principle, it would make it clear to chemical users that paraformaldehyde should not necessarily be considered safer than formaldehyde.
- On the other hand, this approach would reduce the level of detail on use information available to the TURA program, because it would not be clear from filer reports which form of the chemical a filer is using. It would also not be discernable whether the quantity reported represented all the formaldehyde reacted into products (in the case of using formalin as a feedstock), or if some percentage were from paraformaldehyde feedstock, and the remainder from the formaldehyde intermediate.

3. Make no change in the status of paraformaldehyde:

- This approach would maintain reporting requirements in their present form.
- Under this approach, a facility using paraformaldehyde as a feedstock in quantities below 25,000 lbs would not be captured under program requirements.
- Advisory Committee members pointed out that designating formaldehyde as a higher hazard substance without designating paraformaldehyde in the same status could communicate to facilities that paraformaldehyde is considered safer than formaldehyde. This would be misleading.

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- ¹ National Library of Medicine, Haz-Map, Occupational Exposure to Hazardous Agent: Formaldehyde. Available at http://hazmap.nlm.nih.gov/cgi-bin/hazmap_generic?tbl=TblAgents&id=271. Haz-Map is an occupational health database designed for health and safety professionals and for consumers seeking information about the health effects of exposure to chemicals and biological agents at work. Haz-Map links jobs and hazardous tasks with occupational diseases and their symptoms. It is one of the products and services made available by the National Library of Medicine's (NLM) Toxicology and Environmental Health Information Program.
- ² Occupational Safety and Health Administration (OSHA), Safety and Health Topics: Formaldehyde Exposure Evaluation. Available at <http://www.osha.gov/SLTC/formaldehyde/evaluation.html>
- ³ International Agency for Research on Cancer (IARC). 2004. Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 88: Formaldehyde, 2-Butoxyethanol and 1-tert-Butoxypropan-2-ol. Available at <http://monographs.iarc.fr/ENG/Monographs/vol88/index.php>
- ⁴ U.S. Environmental Protection Agency, Office of Pesticide Programs: Reregistration Eligibility Decision for Formaldehyde and Para-formaldehyde (June 2008). Available at <http://www.epa.gov/oppsrd1/reregistration/REDS/formaldehyde-red.pdf>
- ⁵ IRIS Toxicological Review of Formaldehyde – Inhalation Assessment (External Review Draft). Available at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614.
- ⁶ Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Available at http://www.nap.edu/catalog.php?record_id=13142
- ⁷ Agency for Toxic Substances and Disease Registry. 1999. ToxFAQs: Formaldehyde CAS #50-00-0. Available at <http://www.atsdr.cdc.gov/tfacts111.pdf>
- ⁸ Bronchi are the large air tubes that connect the trachea to the lung and carry air to and from the lungs. Bronchitis is an inflammation of the bronchi. Bronchitis causes coughing (this often results in excretion of yellow or greenish mucus), shortness of breath, and chest tightness. Available at <http://www.nlm.nih.gov/medlineplus/ency/article/001087.htm>
- ⁹ U.S. Environmental Protection Agency. Technology Transfer Network Air Toxic Website: Formaldehyde." Available at <http://www.epa.gov/ttn/uatw/hlthef/formalde.html>
- ¹⁰ National Center for Environmental Health. Formaldehyde Exposure in Homes: A Reference for State Officials to Use in Decision-Making. 2008. Available at http://www.cdc.gov/nceh/ehhe/trailerstudy/pdfs/08_118152_Compndium%20for%20States.pdf
- ¹¹ Agency for Toxic Substances and Disease Registry, Medical Management Guidelines for Formaldehyde. Available at <http://www.atsdr.cdc.gov/mhmi/mmg111.html>
- ¹² International Agency for Research on Cancer, Agents Reviewed by the IARC Monographs: Volume 1-100A. Available at <http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf>
- ¹³ National Academy of Sciences, "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," April 2011.
- ¹⁴ National Academy of Sciences, "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," April 2011. An assessment by a working group of scientists at IARC in October, 2009 concluded that there is a strong association between formaldehyde and leukemia (particularly myeloid leukemia). Baan, R. et al. (2009). A Review of Human Carcinogens – Part F: Chemical Agents and Related Occupations. *The Lancet Oncology*, Volume 10 (12): 1143-1144.
- ¹⁵ National Toxicology Program, Formaldehyde (Gas): CAS No. 50-00-0. Available at <http://www.ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s089form.pdf>
- ¹⁶ U.S. Environmental Protection Agency, Integrated Risk Information System: Formaldehyde (CASRN 50-00-0). Available at <http://www.epa.gov/iris/subst/0419.htm>
- ¹⁷ National Toxicology Program, NIEHS, Jan 22, 2010, "Final Report on Carcinogens Background Document for Formaldehyde," prepared to assist with the scheduled review of formaldehyde in the upcoming NTP 12th Report on Carcinogens. Available at: http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/November/Formaldehyde_BD_Final.pdf
- ¹⁸ US EPA, "IRIS Toxicological Review of Formaldehyde – Inhalation Assessment (External Review Draft)," June 2010. Available at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614, viewed May 2011.
- ¹⁹ National Cancer Institute. 2009. Factsheet: Formaldehyde and Cancer Risk. Available at http://www.cancer.gov/images/documents/687f2693-82b5-4ec7-9c6f-e4e917d6ee53/Fs3_8.pdf
- ²⁰ International Agency for Research on Cancer, Summary Data Reported and Evaluation, Formaldehyde (Group 1) CAS No.: 50-00-0. Vol.: 88 (2006). Available at <http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf>

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- ²¹ Collaborative on Health and the Environment (CHE) CHE is a global partnership of over 3,500 individuals and organizations in 45 countries and 48 states, including representatives of patient organizations, health professional and scientific societies, community organizations, environmental health advocates, funders and indeed all those interested in working together to improve public and individual health.
- ²² Rumchev KB, Spickett JT, Bulsara MK, et al (2002). Domestic Exposure to Formaldehyde Significantly Increases the Risk of Asthma in Young Children, *European Respiratory Journal*. 20:403-408.
- ²³ Garrett MH, Hooper MA, Hooper BM, et al (1999). Increased Risk of Allergy in Children Due to Formaldehyde Exposure in Homes, *European Journal of Allergy and Clinical Immunology*. 54:330-337.
- ²⁴ Massachusetts Toxics Use Reduction Institute, Five Chemicals Alternatives Assessment Study: Chapter 4 – *Formaldehyde*. Available at http://www.turi.org/library/turi_publications/five_chemicals_study
Although the wood adhesive industry is the largest consumer of formaldehyde in the U.S., it is not a significant industry in Massachusetts.
- ²⁵ This decrease is most likely explained by manufacturing of printed wiring boards moving overseas.
- ²⁶ The threshold for reporting under Tier II for formaldehyde is 500 lbs.
- ²⁷ Information in this section is drawn from U.S. Environmental Protection Agency, Design for the Environment (DfE). 1998. Alternative Technologies for Making Holes Conductive: Solutions for Printed Wiring Board Manufacturers. Available at <http://www.epa.gov/dfepubs/pwb/pdf/ctsawire.pdf>
- ²⁸ Except where otherwise noted, information on alternatives for building materials is drawn from Toxics Use Reduction Institute, *Five Chemicals Alternatives Assessment Study* (Toxics Use Reduction Institute, 2006). Available at http://www.turi.org/library/turi_publications/five_chemicals_study
- ²⁹ Sivasubramanian, S., Reynaud, E., and Schmidt, D. (2009). Alternative Formaldehyde-Free Particleboard Compositions Based on Epoxidized Vegetable Oils. University Research in Sustainable Technologies Program, Toxics Use Reduction Institute, University of Massachusetts Lowell. Available at <http://faculty.uml.edu/ereynaud/TURIREport09.pdf>
- ³⁰ International Agency for Research on Cancer. 1999. Monographs on the Evaluation of Carcinogenic Risks to Humans: Group 2A – Probably Carcinogenic to Humans, Volume 11, Suppl. 7, Volume 71. Available at <http://monographs.iarc.fr/ENG/Classification/crthgr02a.php>
- ³¹ U.S. Environmental Protection Agency, Integrated Risk Information System: Epichlorohydrin (CASRN 106-89-8). Available at <http://www.epa.gov/iris/subst/0050.htm>
- ³² Li, Xin; Li, Yonghui; Zhong, Zhikai; Wang, Donghai; Ratto, Jo; Sheng, Kuichuan; Sun, Xiuzhi. 2009. Mechanical and Water Soaking properties of Medium Density Fiberboard with Wood Finer and Soybean Protein Adhesive, *Bioresource Technology*. 100: 3556-3562.
- ³³ Global Insight. (2007). Socio-Economic Benefits of Formaldehyde to the European Union (EU 25) and Norway. Available at <http://www.formaldehyde-europe.org/fileadmin/formaldehyde/PDF/Socio-Economic-Benefits-Study.pdf>
- ³⁴ Phosphinocarboxylic acid is a mixture polyphosphinoacrylic acid, phosphonoalkylpolycarboxylic acid and a phosphorous catalyst which can contain sodium monophosphate or sodium hypophosphite. Patent Storm, Non-formaldehyde Durable Press Finishing for Cellulosic Textiles with Phosphinocarboxylic Acid. Available at <http://www.patentstorm.us/patents/5496477/fulltext.html>
- ³⁵ Yang, C. Q., and Chen, D. 233rd ACS National Meeting, Chicago, IL, United States, March 25-29, 2007.
- ³⁶ Use of formaldehyde in fertilizers is not covered here because the TURA program does not believe this is a significant use in Massachusetts industry. However, some information on this topic has been collected in a separate background document in case it is needed at a later point.
- ³⁷ Massachusetts Toxics Use Reduction Institute, Five Chemicals Alternatives Assessment Study: Chapter 4 – *Formaldehyde*. Available at http://www.turi.org/library/turi_publications/five_chemicals_study
- ³⁸ Massachusetts Office of Consumer Affairs and Business Regulation (OCABR), Division of Professional Licensure, 240 CMR 3.0: Salons. Available at <http://www.mass.gov/?pageID=oacaconstituent&L=2&L0=Home&L1=Licenses&sid=Eoca>. Section 3.03: Equipment and Hygiene Procedures: Item 14: “After cleansing and sanitizing, all equipment must be kept in sanitary containers, cabinets or sterilizers. Dry sanitizer must be used in drawers.”
- ³⁹ Massachusetts Office of Consumer Affairs and Business Regulation (OCABR), Division of Professional Licensure, 240 CMR 3.0: Salons. Available at <http://www.mass.gov/?pageID=oacaconstituent&L=2&L0=Home&L1=Licenses&sid=Eoca>. Section 3.03: Equipment and Hygiene Procedures: Item 17: (17) One of the following methods must be used to sanitize instruments and equipment after use on any patron or model: (a) Physical Agents. 1. Boiling water at 212°F for 20

minutes. 2. Steaming dry heat. 3. 70% grain or denatured alcohol for at least ten minutes. 4. Ultra-violet rays in an electrical sanitizer. 5. Immersion in 10% formalin for at least ten minutes. (b) Chemical Agents. 1. Antiseptics and disinfectants (hospital grade required). Vapors, formalin and steri-dry. (c) Bleach. ...”

⁴⁰ National Interstate Council of State Boards of Cosmetology, Inc., “Policies.” Available at <http://www.nictesting.org/policies.htm>.

⁴¹ Arlene Alpert, *Milady's Standard Cosmetology*, 2008.

⁴² The Massachusetts Healthy Nail Salon Workgroup has included representatives from research institutions, Mass Dept of Public Health, Mass Dept of Labor, various town/city boards of health departments, worker and public advocacy organizations, industry representatives, and TURI.

⁴³ The specimen alternatives are Formalternate by Flinn Scientific (a combination of propylene glycol, ethylene glycol phenol ether and phenol); Wardsafe by Ward Scientific (consisting primarily of glutaraldehyde); and S.T.F. (Streck Tissue Fixative) Preservative by Nebraska Scientific (contains diazolidinyl urea, 2-Bromo-2-nitropropane-1, 3-diol (Bronopol), zinc sulfate, and sodium citrate). Each of these alternatives poses some health concerns as well.

⁴⁴ Mao, Chengchen; Woskie, Susan. 1994. Formaldehyde Use Reduction in Mortuaries. Toxics Use Reduction Research Fellow Program Available at <http://www.turi.org/content/view/full/4361>

⁴⁵ With respect to intact bodies, the average embalming time is approximately two hours.

⁴⁶ Additional information on these alternatives: *Glutaraldehyde*: glutaraldehyde may be used as an alternative to formaldehyde in embalming fluids. Glutaraldehyde has similar chemical reaction to tissues as formaldehyde. Compared to formaldehyde, glutaraldehyde-based solutions are considered more efficient and effective disinfectants. Glutaraldehyde diffuses and penetrates into tissue cells more evenly than formaldehyde and can provide a more natural coloration of tissues. As glutaraldehyde combines with proteins and tissues, it changes the nature of proteins and makes them unsuitable as food for bacteria. Higher concentrations of glutaraldehyde may improve protein fixation in human bodies. With respect to embalming, the optimum concentration range may be between 1 and 1.5 percent of aqueous solutions. Aqueous solutions of glutaraldehyde can react with water to produce a variety of byproducts such as 4-formyldec-4-enedial, 2,6-dihydroxyoxane, and Poly(2,6-dihydroxyoxane), which may reduce its effectiveness as a fixative agent in embalming. *Phenoxyethanol*: use of phenoxyethanol may reduce formaldehyde use and exposure by lowering the volume and concentration of formaldehyde in embalming fluids. Phenoxyethanol has excellent tissue preservation properties. However, the procedure involved in using phenoxyethanol as a preservative, which may require submerging the body in approximately 200 liters of 1 percent phenoxyethanol solution, is most applicable for body preservation for teaching laboratories.

⁴⁷ Center for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) Pocket Guide to Chemical Hazards: Glutaraldehyde (CAS No. 111-30-8). Available at <http://www.cdc.gov/niosh/npg/npgd0301.html>

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⁴⁹ Emergency Planning and Community Right-to-Know (EPCRA), Section 313: Chemical List for Reporting Year 2009. Available at <http://www.epa.gov/tri/trichemicals/chemical%20lists/RY2009ChemicalList.pdf>

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