

## **I. Executive Summary**

### **A. Introduction**

During the 1980s, Vermonters expressed growing concern over the potential health and environmental effects of unregulated toxic air pollutants in the state's air-shed. Responding to this concern, the Vermont Agency of Natural Resources (hereafter referred to as "the Agency") proposed "Regulations for the Control of Hazardous Air Contaminants." One aspect of these regulations required a source to determine its own emissions and effect on air quality, and then to add these emissions to existing levels in order to determine if the source in question "caused or contributed to" a violation of the state ambient air quality standard for a hazardous air contaminant.

To address difficulties in implementation surrounding this provision, two actions were taken in 1993. First, after much public deliberation, the Agency amended the regulations and suspended the requirement to consider existing air quality. This suspension was for a five year period, pending a review of the air quality standards for hazardous air contaminants. This review was to be conducted based on the best available scientific information on health effects and risk, and the achievability of these ambient air standards. Section 5-261(6)(c) of the 1993 amended regulations states, "As expeditiously as practicable, but no later than January 1, 1998, the Secretary shall review each Hazardous Ambient Air Standard for the contaminants listed in Appendix C, Category I and the method for their derivation specified in Appendix D to assure that each such standard represents a level requisite to protect the public health." All parties agreed more information was needed on existing levels of air toxics throughout the State of Vermont.

In response to the need for more air toxic data in ambient air, the second action was the establishment of the Hazardous Air Contaminant Monitoring Program. Act 92 of the 1993 Adjourned Legislative Session directed the Agency to establish a Hazardous Air Contaminant Monitoring Program with the following goals:

- (1) Measure the presence of hazardous air contaminants in ambient air;
- (2) Identify sources of hazardous air contaminants;
- (3) Assess human health and ecological risk to focus studies on those air contaminants which pose the greatest risk;
- (4) Gather sufficient data to allow the Secretary to establish appropriately protective standards; and
- (5) Ensure adequate data are collected to support the state's operating permit program.

Act 92 provided funding for this effort by placing a \$1 surcharge on motor vehicle registrations beginning January, 1994, and a surcharge on industrial emissions based on the toxicity of chemicals emitted. These fees and the program will sunset if not re-authorized by July 1998.

## **B. Review of Hazardous Ambient Air Standards**

To assist in the first action of reviewing the methodology used to derive the ambient air standards for toxic pollutants, the Agency appointed a Toxicological Advisory Committee (“the Committee”). The Committee consists of toxicologists and scientists from varying backgrounds, representatives of the State’s Department of Health and Department of Environmental Conservation, and representatives of the major interest groups involved with the air toxic program including the Vermont Public Interest Research Group and the Associated Industries of Vermont. A complete list of the Committee members is found in Appendix E. The recommendations contained in this report reflect the general consensus of the Committee.

The Committee has reviewed the methodology for deriving the Hazardous Ambient Air Standards (HAAS) for Categories I, II and III compounds listed in Appendix C of the 1993 amended regulations. Per the current Regulations, Category I Compounds are those Hazardous Air Contaminants identified as potentially carcinogenic by the United States Environmental Protection Agency (US EPA) or International Agency for Research on Cancer (IARC) or reported to induce cancer in two or more tests performed by either the National Toxicological Program (NTP) or National Cancer Institute (NCI). Antimony trioxide and acrylamide were also placed in this Category due to their identification as potential human carcinogens by the American Conference of Governmental Industrial Hygienists (ACGIH) and Dr. Edward Calabrese of the University of Massachusetts. Category II Compounds are noncarcinogens with potential chronic/systemic effects due to long term exposure and Category III Compounds are noncarcinogens considered to have primarily short term irritant effects.

### **1. Category I Compounds**

After reviewing Appendix D of the Regulations, the Committee is now recommending modifying the criteria for placing a chemical on Category I. The Committee now proposes that a chemical be placed on Category I if it is identified as potentially carcinogenic by the US EPA or IARC and may be considered for inclusion if positive tests in two or more species are reported by NTP. This change of requiring positive tests in two or more species is consistent with the EPA and IARC methodology for determining if a compound is potentially carcinogenic. The Committee has determined that both NCI and NTP need not be consulted in determining whether a compound is potentially carcinogenic. This is because the NCI carcinogenesis Bioassay Program has been part of the National Institute for Environmental Health Sciences since 1981 at which time NTP became responsible for conducting the carcinogenicity/toxicity studies.

There are currently 54 compounds on the Category I list. The Agency has determined that all but six compounds (arsine, 1,1-biphenyl, diazomethane, methyl bromide, methyl iodide and propylene imine) of the current Category I compounds meet the above proposed revised requirements for classification as a Category I contaminant. The Committee recommends that these six compounds be removed from Category I and be placed in Category II. Standards for the remaining 48 Category I compounds have been updated using the most current toxicity information. The Agency has determined that 14 compounds currently classified as Category II or III meet the proposed revised criteria for classification as Category I. The majority of the Committee

proposes that these 14 compounds be placed on Category I and the standards be updated using the Category I methodology.

The Committee also proposes the following revisions to deriving Category I ambient standards:

- (1) employing a conservative absorption factor of 100% or 1;
- (2) if an inhalation potency factor is unavailable, employing an oral potency factor as a surrogate unless carcinogenicity is unique to ingestion route of exposure;
- (3) if neither an inhalation nor an oral potency factor exists, employing an inhalation reference concentration divided by an uncertainty factor of 10 to account for carcinogenicity; and
- (4) if a potency factor or reference concentration is not available, the Committee recommends retaining the default standard as the ambient standard.

## **2. Category II and III Compounds**

There are currently 44 Category II and 192 Category III compounds. At present, the Regulations require that the HAAS for Category II and III compounds be based upon the ACGIH Threshold Limit Values (TLVs) which are work place guidelines. Ambient standards for these compounds are derived by dividing the TLV, when one is available, by one or more uncertainty factors.

Per the current Regulations, if a TLV is not available for a particular compound, then, if available, the Agency shall use an occupational standard established by either the National Institute for Occupational Safety and Health (NIOSH)(termed Recommended Exposure Limits or RELs) or the US Department of Labor Occupational Safety and Health Administration (OSHA)(termed Permissible Exposure Limits or PELs) as a surrogate in the ambient standard derivation process. If no occupational value is available from any of these sources, a standard is issued based on an evaluation of the toxicity information available for the compound in question.

The Committee recommends changing the above methodology to derive the standards for Category II and III compounds. Inhalation reference concentrations (RfCs) are proposed to be used as the basis for ambient standards. RfCs are designed to be protective of potential noncarcinogenic health effects given long term, continuous exposure.

If chemical specific RfCs are not available, the Committee recommends using the most conservative of the TLV, PEL, or REL as the basis of the HAAS. It is also recommended that a simple mechanism be developed to allow for the consideration of updated, scientific information that supports using an occupational standard other than the most conservative one as the basis of the HAAS.

If no RfC or occupational value is available, a standard will be issued based on an evaluation of the toxicity information available for the compound in question.

In addition, the proposed revised methodology for Category II and Category III compounds includes employing an extra uncertainty factor of 10 to derive the HAAS for those Category II and Category III compounds identified as a potential occupational carcinogen by NIOSH or as an A1: Confirmed Human Carcinogen; A2: Suspected Human Carcinogen; or A3: Animal Carcinogen by ACGIH.

Finally, the Committee recommends comparing the HAAS to short term exposure limits called Acute Exposure Guidelines (AEGs), to determine if the standard is sufficiently protective. Future efforts should focus on developing short term ambient standards to protect against potential adverse health effects that may be associated with acute or short term exposures.

### **C. Hazardous Air Contaminant Monitoring Program**

In order to compare ambient air levels to the standards, the Agency has reviewed air monitoring data from 1993 to 1995. The Air Monitoring Data shows that there are nine compounds whose air concentrations are consistently above the current standards. Those compounds are benzene, 1,3-butadiene, carbon tetrachloride, chloroform, formaldehyde, methyl chloride, methylene chloride, tetrachloroethylene, and 1,2,4-trimethyl benzene. Due to public concern, the Agency is also concerned about styrene, acrolein and mercury. Based on updated toxicity information, current air concentrations of tetrachloroethylene and 1,2,4-trimethyl benzene would no longer exceed the proposed revised standards, however, acrolein's concentrations would now exceed the proposed revised standard. Out of the eight compounds that would consistently exceed the proposed revised standard, five are considered to be generated locally, and three are considered to be transported from other areas. The local pollutants are benzene, 1,3-butadiene, formaldehyde, methylene chloride and acrolein. The transported pollutants are carbon tetrachloride, chloroform, and methyl chloride. Of the locally generated compounds listed above, benzene, 1,3-butadiene, formaldehyde and acrolein are all byproducts of combustion.

### **D. Discussion of Risk**

Since the Agency is responsible for ensuring public health protection from outdoor exposures to toxic air pollutants, the Agency believes it is prudent to establish ambient air standards adequate to protect public health with an ample margin of safety. For carcinogens, where it is assumed there is no absolutely risk-free level of exposure, it becomes necessary for the Agency to establish a maximum allowable level of incremental lifetime carcinogenic risk (hereafter incremental lifetime carcinogenic risk is referred to as "risk"). This maximum allowable level of risk represents a negligible increase in potential risk over background risk over a lifetime of exposure, for the population of concern. Various federal and state agencies employ different levels of maximum allowable risk or negligible risk. Values between one and one million ( $1 \times 10^{-6}$ ) to one in ten thousand ( $1 \times 10^{-4}$ ) are typically used. The maximum allowable level of risk is a risk management decision that must be made by the Agency of Natural Resources, in consultation with the Department of Health, and therefore the Committee is not recommending any specific risk level at which ambient standards should be established. However, the Committee does agree that  $1 \times 10^{-6}$  is a negligible risk.

Deciding what amount of potential risk is to be considered negligible is a complex task. However, whether or not it is acceptable to allow additional emissions even at this negligible level should depend on a consideration of existing ambient air quality. For example, if risk associated with inhalation of existing ambient air is estimated to already be highly elevated, above  $1 \times 10^{-4}$  for example, it may not be appropriate to allow additional emissions, even at the  $1 \times 10^{-6}$  level, without further investigation.

The Committee agrees that it may be prudent to define a total ambient air quality goal that should not be exceeded. Individual point sources would then be required to control emissions so that the total risk associated with inhalation of ambient air is below the total ambient air quality goal.

### **E. Recommendations for Future Actions**

1. The Committee recommends the continued reliance on EPA and IARC for the purposes of classification of known or potential carcinogens (Category I compounds). The Committee further recommends that a compound may be considered for inclusion into Category I if positive cancer tests in two species are reported by NTP.
2. The Committee recommends the current methodology for establishing risk-based standards for known or potential carcinogens be retained using the most recent cancer potency factors developed by EPA. The one suggested change to the methodology is to use a conservative absorption factor of 100 percent for all Category I compounds. The Committee recommends the Agency allow for the consideration of the use of a factor other than 100 percent where toxicological information is presented to support an alternative value.
3. For known or potential carcinogens without EPA cancer potency factors, the Committee recommends revising the current methodology to allow the use of inhalation reference concentrations (RfCs) divided by an additional uncertainty factor of 10. In the absence of cancer potency factors and RfCs, the Committee recommends that a default concentration of 0.01 micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ) be retained.
4. For those non-cancer compounds (Category II & III) where RfCs have been developed by EPA, the Committee recommends using RfCs as the basis for air standards instead of modified occupational levels. For those Category II and III compounds where an RfC has not been established, the Committee recommends using the lower of the TLV, PEL, or REL value as the basis for the modified occupational standard. In addition, if a Category II or III compound is considered an occupational carcinogen by NIOSH or ACGIH, the Committee recommends dividing the standard by an additional uncertainty factor of 10.
5. The Committee suggests continuing the air monitoring program for air toxics to determine ambient levels and to observe any trends as regulatory actions are implemented. The air monitoring data allows the Agency to compare ambient air levels to the standards to determine those compounds that consistently exceed the standard.

6. The Committee recommends developing a Toxic Air Action Plan to discuss methods of reducing emissions of those locally generated compounds that consistently pose a public health concern.
7. The Committee recommends conducting a review of standards every five years so that standards can be updated based on the most recent toxicological information. The Committee recommends using the proposed revised methodologies for reviewing the standards. If during the five year periodic update it is determined that a change in toxicity information will significantly impact the standard, the Agency should consider a single regulatory amendment to revise the standard (s).
8. The Committee recommends developing short term air standards for some Hazardous Air Contaminants to protect against potential adverse health effects that may be associated with acute or short term exposures. In the interim, as a temporary measure, the Committee recommends establishing the environmental level for these contaminants as the occupational ceiling limit.
9. The Committee suggests considering other endpoints in addition to carcinogenic endpoints in order to determine if the current standards are protective. The Committee suggests considering other endpoints such as endocrine disruptors and environmental respiratory disease in future regulatory decisions.