Synopsis of Scientific Justification for Ohio Administrative Code (OAC) 3745-114
Toxic Air Contaminants

A. RULE SYNOPSIS

The Ohio EPA Division of Air Pollution Control (DAPC) has completed rule language that fulfills the requirements of Amended Substitute Senate Bill 265 (SB 265) of the 126th General Assembly signed into law on May 2, 2006. SB 265 amends language in section 3704.03 of the Ohio Revised Code (ORC) that results in a streamlining of the permitting process for minor sources of air pollution. The rule language addresses the portion of SB 265, contained in ORC 3704.03(F)(3)(c) and (F)(4), that gives the Ohio Environmental Protection Agency (Ohio EPA) authority over toxic emissions. New rule 3745-114-01, "Toxic Air Contaminants," incorporates the list of air contaminants that meets the requirements of SB 265. On June 20, 2006, a draft of this rule was sent out to interested parties and posted on DAPC's World Wide Web site for a 30-day informal comment/review period. On July 19, 2006, interested parties were notified the comment period would be extended an additional 30 days. After review of interested party comments, Ohio EPA prepared a rule for proposal after toxicologists further reviewed all the toxic air contaminants in the draft rule and reduced the number of compounds based on a refined screening technique described in the next section. Originally 639 compounds were included in the draft rule. This was reduced to 303 compounds under the proposal provided on September 15, 2006. Comments were accepted on this proposal and a public hearing was held on October 23, 2006. After consideration of comments, the rule, as proposed, has been submitted for final adoption.

B. SCIENTIFIC EVIDENCE SYNOPSIS

<u>Introduction</u>

Ohio EPA is also required under ORC 3704.03(F)(3)(c) to identify the scientific evidence relied upon in making the determination for inclusion of the air contaminants in OAC 3745-114-01. Under this section, Ohio EPA identifies the sources used to identify toxic air contaminants that meet the criteria contained in ORC 3704.03(F)(3)(c). This section also identifies the logic used in adding and removing compounds from the draft rule. You will also find attached to this rule package the scientific evidence documents for each individual air contaminant included in the proposed rule (see the document entitled "Toxic Compound Data Sheets."). The scientific justification for inclusion of each air contaminant in this rule is included on these sheets.

Ohio Revised Code (ORC) 3704.03(F), amended by SB 265 of the 126th General Assembly (herein referred to as "toxics statute") authorizes the Ohio EPA to promulgate

rules which contain a list of air toxic compounds that are to be examined in the State of Ohio in accordance with the toxics statute. An air contaminant is defined in the toxics statute as a compound that "presents, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects, including, but not limited to, substances that are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, or neurotoxic, that cause reproductive dysfunction, or that are acutely or chronically toxic, or a threat of adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise, and that is identified in the rule by chemical name and chemical abstract service number."

This document is intended to provide the rational for the selection of compounds that the Ohio EPA has determined meet the above statue and that are included in the subsequent proposed toxic rule in OAC 3745-114-01. This rational was developed by Ohio EPA staff in response to the plain language of the toxics statute, a detailed evaluation of the toxicology information from many sources described later, and the comments provided by commentors concerning the previously issued interested party rule package.

The first step in creating this list was to identify chemical compounds that appeared to meet the various triggers identified in the toxics statute. This was done by reviewing the plain language of the toxics statute and comparing this language to compounds listed in various toxic lists. Compounds were added to the list when judged to meet one or more of the requirements outlined or specified in the toxics statute language. The following rational was used in the decision process:

Potential air contaminants were included on the list following the definition of toxic included in the toxics statute. Included in the initial draft air toxic compounds list were included in the draft list that were determined to:

"presents, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects, including, but not limited to, substances that are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, or neurotoxic, that cause reproductive dysfunction, or that are acutely or chronically toxic, or a threat of adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise...".

Compounds were cross-referenced to be included on the toxic compound list by the above definition, based on the information included in one or more of the following sources or databases containing detailed toxicological information about the compounds of concern:

- U.S. EPA's list of Hazardous Air Pollutants [HAPs] and Health Affects Notebook
- U.S. EPA's Integrated Risk Information System [IRIS]
- U.S. EPA's National Air Toxics Assessment [NATA]

- The Agency for Toxic Substances and Disease Registry (ATSDR)Minimal Risk Levels (MRLs) for Hazardous Substances and Toxicological Profiles
- The American Conference of Governmental and Industrial Hygienists (ACGIH)
- The International Agency for Research on Cancer (IARC)
- The National Toxicology Program (NTP) [U.S. Dept. of Health and Human Services]
- U.S. EPA's Accidental Release Prevention Program [112r]
- U.S. EPA's Persistent Bioaccumulative and Toxics Pollutant Strategy [PBTs]
- U.S. Department of Health and Human Services Hazardous Substances Data Bank

Second, certain compounds were determined to have a negligible risk by reviewing the ACGIH Threshold Limit Values (TLVs). Compounds with ACGIH Threshold Limit Values greater than 1,000 milligrams per meter cubed (mg/m^3) [1,000,000 ug/m^3] were initially removed from the list.

Third, Ohio EPA developed a list of screening criteria to further refine the list of over 600 compounds, based on the below described criteria.

1. Individual compounds could be grouped with an expanded class or definition of compounds.

    a. Some compounds belong to a larger class of compounds that better match the description of the toxic compound, containing the specific element or part of the toxic compound of interest. For example, chromium and chromium compounds are grouped together in the proposed list. It is the full intention of the Ohio EPA to review variations of compounds that are listed as a group in the final list.

    b. Some compounds and classes of compounds remain grouped by U.S. EPA in the CAA or other programs. For example, dioxins, furans, glycol ethers remain grouped by definition in the list of Hazardous Air Pollutants in the CAA. It is the full intention of Ohio EPA and U.S. EPA to review all congeners, derivatives, or other similar compounds that are grouped in this manner.

    c. Some compounds on the original list were inadvertent duplicates of previously listed compounds; duplicates were removed.

2. Some compounds are negligible risk air pollutants, demonstrating low toxicity.

    a. Compounds with low inhalation toxicity values (such as those with very high ACGIH threshold limit values (TLVs)) were removed from the list. These compounds would have to be emitted at excessive and impractical emission rates to exceed the maximum acceptable ground level concentration (MAGLC) prescribed by the statute for the toxic evaluation.

b. Compounds whose TLVs were based upon irritation only, citing mild or no other human health toxic effects, were removed from the list. For example, some TLVs or other limits were derived based solely upon irritation-only effects to workers exposed to high concentrations of the compound in an industrial setting. It is unlikely that MAGLC concentrations would be exceeded in an air pollution permit.

c. Compounds demonstrating limited evidence for toxic effects in humans, especially through the inhalation route of exposure, were removed from the list. Some compounds have an extrapolated inhalation toxicity value derived from an oral or dermal route of exposure, with little or no evidence for toxic effects in humans at the prescribed air concentrations. This occurs when a compound is clearly toxic by ingestion (oral) or application to the skin (dermal), but the inhalation toxicity number is derived from calculations based on the oral and dermal toxicological effects. While these derived numbers are important and useful, the precise scientific reasoning behind the calculated number is less robust than exposure limits derived from inhalation or human occupational exposure studies.

d. In some cases, inhalation toxicity numbers were derived from a single, or a few, emergency air release events that caused a large dosage to the exposed population, resulting in toxic effects. Inhalation toxicity values derived from evidence collected as the result of a sudden, short duration (acute) exposures yield protective numbers for future emergency release events. While these toxicity values are important for such sudden, large releases, they are of limited use when directly applied to the evaluation of potential air permit sources, that in general emit pollutants continually for a long-term (chronic) duration. In many cases, the risk from low level chronic exposure to the compound is minimal. For these cases, the compounds were removed from the list.

3. Inhalation route unlikely for realistic exposure scenarios in Ohio.

a. As an extension of reason (2)(c) above, compounds with high oral or dermal toxicity in many cases are not likely to be released to the atmosphere in a manner to cause inhalation exposure. Specifically, these compounds are not likely to released in a particulate or vapor state, when it is possible for them to be inhaled into the lungs. Compounds that met this condition were removed from the list.

b. Some compounds are no longer produced, manufactured, or otherwise used in Ohio or, in some cases, the entire United States. Databases within the Ohio EPA's Division of Air Pollution Control were linked and cross-checked with federal information to investigate and confirm certain specific compounds lack of use. Compounds that met this condition were removed from the list.

i. Ohio EPA intends to add any of these compounds to the list at a later date if a manufacturing level of production is ever resumed within the State.

ii. Compounds that are banned, or of limited restricted use by U.S. EPA or applicable governmental body were removed from the list, except in the specific case of Persistent, Bioaccumulative and Toxic compounds, that are listed and defined by U.S. EPA.

4. Compounds in consumer products, or designated for specific consumer or agricultural uses.

   a. Pesticides (insecticides, rodenticides, fungicides, herbicides, etc.) or other household or agricultural use pest removal products were removed from the list.

      i. These compounds are generally emitted through the use of household or agricultural products and are not typically released from industrial processes.

      ii. Application of many of these products is regulated and licensed by the Department of Agriculture, for limited home or specific agricultural use.

   b. Compounds whose route of human exposure results exclusively or primarily from use in food, food handling, packaging and storage, or cosmetic products were removed from the list. Inhalation exposure resulting from use of these products is unlikely, and not covered by the requirements of an air pollution permit.

      i. Ohio EPA reserved the ability to examine any potential new industrial source of these compounds through addition to the list if necessary.

5. Contrary to the above criteria, the following compounds were retained on the list

   a. Compounds listed as Hazardous Air Pollutants (HAPs) by U.S. EPA in the CAA.

      i. Compounds de-listed from the federal list of HAPs through the petition process, were, upon toxicological examination, removed from the Ohio list.

      ii. Other miscellaneous compounds that, based on the professional judgment of the Ohio EPA air pollution toxicologists, should be regulated under the air permit program.

   b. Compounds listed by U.S. EPA as Persistent, Bioaccumulative, or Toxic by U.S. EPA (including specific pesticides) remain on the list.

As a result of the final screening of the list, the list was paired down to 304 compounds which Ohio EPA believes are appropriate to regulate under Ohio's air toxic program.

National and international sources of current toxicological information

The U.S. EPA's Hazardous Air Pollutants [HAPs].

The Clean Air Act Amendments of 1990 required U.S. EPA to issue standards over a 10 year period regulating emissions of 189 toxic air pollutants from various industries and other sources. The list of hazardous air pollutants was derived from several sources: Section 313 of the Superfund Amendments and Re-authorization Act (SARA 313), Section 104 of the Comprehensive Emergency Response and Compensation Liability Act (CERCLA 104), U.S. EPA's National Air Toxics Information Clearinghouse (NATICH) database of chemicals, U.S. EPA's National Emission Standards for Hazardous Air Pollutants (NESHAPs), National Ambient Air Quality Standards (NAAQS), the Office of Toxic Substances (OTS), and data from the National Toxicology Program (NTP). The health effects notebook contains fact sheets on hazardous air pollutants that present hazard, based on scientific studies of exposure to humans and other mammals. While the 1970 Clean Air Act gave U.S. EPA authority to list and regulate air toxics chemicals, Section 112 of the 1990 Act included a list of 189 hazardous air pollutants selected by Congress on the basis of potential health and/or environmental hazard. In addition, the 1990 Act allows EPA to add new chemicals to the list as necessary. To regulate HAPs, U.S. EPA must identify categories of sources that released HAP chemicals. Once the categories of sources were listed, EPA proceeded to issue Maximum Achievable Control Technology (MACT) regulations to reduce HAP pollutant releases.

Approximately 45 percent of the chemicals included on the list of HAPs have been evaluated for potential carcinogenicity. An estimate of these chemicals according to the Agency's classification scheme for weight-of-evidence is: Group A - 13 percent (known human carcinogens), Group B - 55 percent (probable human carcinogens), Group C - 13 percent (possible human carcinogens) and Group D - 19 percent (not classifiable).

U.S. EPA's Integrated Risk Information System [IRIS].

The U.S. EPA's IRIS contains information on human health effects that may result from exposure to various chemicals in the environment. This information represents a consensus opinion of U.S. EPA health scientists interpreting the scientific literature applicable to health effects of a chemical, and using established methodologies to develop values for oral reference dose, inhalation reference concentration, carcinogenic slope factor and unit risk. Cancer causing, and non-cancer causing toxic compounds are summarized in IRIS and have been subject to U.S. EPA's peer review policy. Also included in the IRIS information is a 'Weight of Evidence' determination for the classification of a compounds as carcinogens.

Health assessment information on a chemical substance is included in IRIS only after a comprehensive review process of chronic toxicity data by both U.S. EPA and external health scientists http://www.epa.gov/IRIS/process.htm). Detailed review of the information for each compound is contained in a Toxicological Review section of the

database.

The IRIS database contains information on human health effects that may result from exposure to various chemicals in the environment. IRIS was developed to provide consistent information on chemical substances for use in risk assessments, decision-making and regulatory activities. The IRIS system is a collection of individual chemical computer files containing descriptive and quantitative information in the following categories: Oral reference doses and inhalation reference concentrations (RfDs and RfCs, respectively) for chronic non-carcinogenic health effects, and hazard identification, oral slope factors, and oral and inhalation unit risks for carcinogenic effects. This information represents a consensus opinion of U.S. EPA health scientists interpreting the scientific literature applicable to health effects of a chemical, and using established methodologies to develop values for oral reference dose, inhalation reference concentration, carcinogenic slope factor and unit risk. The products of this work, summarized in IRIS and elaborated in chemical-specific Toxicological Profile documents, have been subject to U.S. EPA's peer review policy. Also included in the IRIS information is a Weight of Evidence determination for the classification of a compounds as a carcinogen. As new scientific information becomes available, U.S. EPA will review it, as appropriate, and revise IRIS files accordingly. Cancer and non-carcinogenic risk values may be used individually, or in concert with other toxicological information in the definition of a maximum allowable ground level concentration (MAGLC).

U.S. EPA's National-Scale Air Toxics Assessment [NATA].

The U.S. EPA's NATA was designed to help U.S. EPA, state, local and tribal governments and the public better understand the air toxics problem in the United States. The most recent NATA toxic compound examination included 177 air pollutants. The assessment included four steps, an inventory of air toxics emissions, estimates of annual average outdoor air toxics concentrations, estimates of exposure concentrations, and a characterization of potential public health risks.
The first assessment (examining 1996 emissions) looked at 32 of the 33 air toxics that U.S. EPA identified in 1999 as potentially posing the greatest threat to public health in the largest number of urban areas. These pollutants were highlighted in U.S. EPA's Integrated Urban Air Toxics Strategy. The 32 air toxics were a subset of U.S. EPA's list of 188 toxic air pollutants plus diesel particulate matter. In February 2006, U.S. EPA released the results of its NATA of 1999 air toxics emissions. The 1999 NATA expanded the air toxics list to include 177 air pollutants (a subset of the air toxics on the Clean Air Act's list of 187 air toxics plus diesel particulate matter).

The Agency for Toxic Substances and Disease Registry's (ATSDR) Minimum Risk Levels (MRLs).

ATSDR is a branch of the Public Health Service, U.S. Department of Health and Human Services. Toxicity assessments are performed by the ATSDR that characterize the toxicological and adverse health effects information for toxic compounds. The profiles

list MRLs that are derived when reliable and sufficient data exist to identify the most sensitive health effects from exposure the compound. An MRL is an estimate of the daily exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specific duration of exposure.

A Toxicological Profile is prepared by their Division of Toxicology according to ATSDR and U.S. EPA guidelines. The Profile succinctly characterizes the toxicological and adverse health effects information for the toxic compound. The peer-reviewed profile lists Minimum Risk Levels (MRLs) that are derived when reliable and sufficient data exist to identify the most sensitive health effects from exposure the compound. An MRL is an estimate of the daily exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specific duration of exposure. MRLs are derived for acute (1-14 days), intermediate (15-364 days) and chronic (365 days and longer) exposure durations. As such, the MRLs define the depth of toxicological information available for a compound declared toxic by the Profile. Values for MRLs may be used to develop the MAGLC for a compound singularly, or in combination with other available toxicological information.

The American Conference of Governmental and Industrial Hygienists (ACGIH).

The American Conference of Governmental and Industrial Hygienists (ACGIH) is a non-governmental scientific organization that reviews the existing, published, peer-reviewed literature in order to publish guidelines known as Threshold Limit Values (TLVs) defining safe levels of exposure to hazardous chemicals in the workplace. TLVs are health-based values created from review of industrial hygiene, toxicology, occupational medicine, and epidemiological studies to determine the level of exposure a typical worker can experience repeatedly without adverse health effects.

The ACGIH also publishes the Documentation for each compound documenting the decision-making process prior to publication of the TLV. The TLVs are used by the Ohio EPA as one method of establishing the maximum acceptable ground level concentration (MAGLC). Safety and time-of-exposure factors are applied to the TLV to generate the MAGLC. The TLV booklet is published annually by the ACGIH, 1330 Kemper Meadow Drive, Cincinnati, Ohio 45240-4148 (www.acgih.org).

The International Agency for Research on Cancer (IARC).

The International Agency for Research on Cancer (IARC) is part of the World Health Organization. The main emphasis of IARC research is on epidemiology, environmental carcinogenesis and research training. IARC focuses its studies on humans, coordinating and conducting both epidemiological and laboratory research into the causes of cancer. As part of IARC’s goal of identifying the causes of cancer, through laboratory investigations, epidemiological studies and working group meetings, more than 900 agents and exposures have been examined with the aim of unambiguously identifying those which cause cancer in humans. Carcinogens are listed by the organization.

IARC's mission is to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer

control. The Agency is involved in both epidemiological and laboratory research and disseminates scientific information through publications, meetings, courses, and fellowships. A major goal of the IARC is the identification of causes of cancer, so that preventive measures may be adopted against them. The main emphasis of IARC research is on epidemiology, environmental carcinogenesis and research training. IARC focuses its studies on human, coordinating and conducting both epidemiological and laboratory research into the causes of cancer. As part of IARC's goal of identifying the causes of cancer, through laboratory investigations, epidemiological studies and working group meetings, more than 900 agents and exposures have been examined with the aim of unambiguously identifying those which cause cancer in humans. Results of these determinations are published in Monographs that are used widely by research scientists, public health authorities and national and international regulatory authorities. Each monograph consists of a brief description, where appropriate, of the potential exposure to the agent or mixture, by providing data on chemical and physical properties, methods of analysis, methods and volumes of production, use and occurrence.

The National Toxicology Program (NTP).

The National Toxicology Program (NTP) is an interagency program (within the U.S. Department of Health and Human Services) whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The program maintains an objective, science-based approach in dealing with critical issues in toxicology and is committed to using the best science available to prioritize, design, conduct, and interpret its studies. To that end, the NTP is continually evolving to remain at the cutting edge of scientific research and to develop and apply new technologies. The NTP publishes a Report on Carcinogens (RoC), an informational scientific and public health document that identifies and discusses agents, substances, mixtures, or exposure circumstances that may pose a hazard to human health by virtue of their carcinogenicity. The RoC compiles information on the carcinogenicity (ability to cause cancer), genotoxicity (ability to damage genes), and biologic mechanisms (modes of action in the body) of the listed substance in humans and/or animals. The RoC is a hazard identification document and does not present quantitative assessments of the risks of cancer associated with exposure to these substances.

Agents, substances, or exposure circumstances are listed as either "known to be a human carcinogen," or "*reasonably anticipated to be a human carcinogen*." The category "*known to be a human carcinogen*" is reserved for those substances for which there is sufficient evidence of carcinogenicity from studies in humans that indicates a causal relationship between exposure to the agent, substance, or mixture and human cancer. The second category, "*reasonably anticipated to be a human carcinogen*" includes those substances for which there is limited evidence of carcinogenicity in humans and/or sufficient evidence of carcinogenicity in experimental animals.

U.S. EPA's Accidental Release Prevention Program [112r].

The Clean Air Act Amendments of 1990 required U.S. EPA to promulgate regulations to prevent accidental releases of regulated substances and reduce the severity of those releases that do occur. The Accidental Release Prevention Requirements: Risk Management Programs under CAA Section 112(r)(7) focuses prevention measures on chemicals that pose the greatest risk to the public and the environment. Under these requirements, industry has an obligation to prevent accidents and operate safely. U.S. EPA published a list of substances that, when involved in an accidental release, could cause death, injury, or serious adverse effect to human health or the environment. Under these requirements, industry has an obligation to prevent accidents and operate safely. Information which summarizes these requirements are called a Risk Management Plan (RMP). Facilities were required to file an RMP with U.S. EPA by June 21, 1999 and with Ohio EPA by January 3, 2000.

U.S. EPA was required to publish a list of 100 substances that, when involved in an accidental release, could cause death, injury, or serious adverse effect to human health or the environment. U.S. EPA's list includes 77 acutely toxic chemicals (thresholds range from 500 - 20,000 pounds) and 63 flammable gases and volatile flammable liquids (10,000 pounds).

U.S. EPA's Persistent Bioaccumulative and Toxics Pollutant Strategy [PBTs].

In 1998 the U.S. EPA released its Agency-wide Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic (PBT) Pollutants (PBT Strategy). The goal of the PBT Strategy is to identify and reduce risks to human health and the environment from current and future exposure to priority PBT pollutants. The PBT Strategy outlines an approach to achieving PBT risk reductions which includes the development and implementation of national action plans for priority PBT pollutants. These plans incorporate U.S. EPA's statutory authorities and national programs, building on work initiated under the Great Lakes Binational Toxics Strategy. The PBT Program is a main focus of the U.S. EPA's Multi-Media and Pollution Prevention (M2P2) Forum.

The first 12 PBTs were identified from the 12 level 1 substances from the U.S. Binational Toxics Strategy (BNS): aldrin/dieldrin, benzo(a)pyrene, chlordane, DDT and its metabolites, hexachlorobenzene, alkyl-lead, mercury and its compounds, mirex, octachlorostyrene, PCBs, dioxins and furans, and toxaphene. PBT pollutants are highly toxic, long-lasting substances that can build up in the food chain to levels that are harmful to human and ecosystem health. They are associated with a range of adverse human health effects, including effects on the nervous system, reproductive and developmental problems, cancer, and genetic impacts. The challenge in reducing risks from PBTs stems from the pollutant's ability to travel long distances, to transfer rather easily among air, water, and land, and to linger for generations in people and the environment. The populations at risk, especially to PBTs such as mercury, dioxins, and polychlorinated biphenyls (PCBs), are children and the developing fetus.

The Hazard Substance Data Bank.

he Hazardous Substances Data Bank is toxicological data file provided by the U.S.

National Library of Medicine's (NLM) Toxicology Data Network (TOXNET®) that focuses on the toxicology of potentially hazardous chemicals. It is enhanced with information on human exposure, industrial hygiene, emergency handling procedures, environmental fate, regulatory requirements, and related areas. All data are referenced and derived from a core set of books, government documents, technical reports and selected primary journal literature. The HSDB is organized into individual chemical records, and contains over 5000 such records. The HSDB is peer-reviewed by the Scientific Review Panel (SRP), a committee of sixteen experts in major subject areas such as toxicology, chemistry, pharmacology, industrial hygiene, medicine, emergency response procedures, environmental science, hazardous waste handling, and regulatory requirements. The panel meets three or four times a year to conduct a comprehensive review of the scientific information in new and updated chemical records.