

An Introduction to Risk Assessment, Risk Management and The Division of Air Quality Air Toxics Program

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Introduction. This brief document is intended to address several common questions concerning North Carolina Division of Air Quality's air toxics program. The air toxics program is a "risk-based" regulatory program designed to protect the public health by limiting emissions of toxic air pollutants from man-made sources. We will begin by first introducing the fundamental concepts of risk, then explain how the toxics program strives to minimize risks to the public related to exposure to air pollutants.

What is risk? Risk is defined as the probability and degree of harm arising from a given situation or activity. Many everyday activities involve risks - some obvious and some not so obvious, some minor and some extreme. For example, driving a car involves taking risks. Driving without a seatbelt involves risk of greater harm. Driving while impaired involves extreme risks of both serious injury to the driver (a risk *assumed* by the driver), as well as risk to other vehicles on the road (a risk *imposed* by the driver on others). Risks surround us in our every day lives and greatly influence many decisions we make.

What are risk assessment and risk management? Simply put, risk assessment is the act of sizing up a situation involving risk. People assess risk in every day situations: for example, noticing that roads are icy might convince a person that driving to the store for groceries is too dangerous. Risk management is the act of taking reasonable and effective steps to minimize risk. Cyclists wear helmets to prevent serious head injuries during accidents. Motorists may choose to wear seatbelts to reduce the risk of injury. Population-level risk management tools are also all around us: for example, speed limits act to reduce the risk of serious injuries to all motorists. Many similar examples can be found in laws governing everyday human activities.



What roles do risk assessment and risk management play in the DAQ air toxics program? We humans encounter risks through chemical exposures every day in the environment around us. In some cases (for example, smoking or drinking) the risks result from willing decisions made by informed individuals. In other cases the risks result from undesired circumstances such as exposure to air and water pollution. The toxics program is designed to protect public health by minimizing exposure to (and risk from) toxic air pollutants emitted from man-made sources. Risk assessment is used to establish protective guidelines for human exposure. The implementation of these guidelines through laws and regulations can be considered an example of risk management.

How does the air toxics program protect public health? The toxics program is designed around a set of Aceptable Ambient Level (AAL) guidelines. "Acceptable" in this context is intended to be a level "below the concentration that would produce adverse health effects in sensitive subgroups of the general population" (NCAS, 1986). Regulated pollution sources are asked to reduce their emissions below those levels that are predicted to exceed the AAL beyond their fence line. The toxics program uses computer-based dispersion models to compare the impact of pollution from a smokestack to the appropriate AAL.

Determining what exposure level is acceptable can be very challenging. The standard approach is to study very closely everything that is known about a pollutant in order to determine the lowest level known to cause harm to people. Then beginning from this starting point, several safety factors are used to reduce that level even further. Safety factors may be used to protect sensitive people such as asthmatics or to take into consideration other possible adverse effects that have not been studied. In some cases, safety factors may be used if a chemical is known to interact with other chemicals to produce greater toxicity. In general, larger safety factors are used when less is known about a chemical. This approach defaults to the protection of public health.

Sample Risk Assessment: Methylene Diphenyl Isocyanate (MDI)	
No Adverse Effect Level:	0.2 mg/m ³ (Starting point, based on study in rats)
Safety Factors:	
• Non-continuous exposure adjustment:	5.6
• Differences between rats and humans:	10
• Accounting for sensitive humans:	10
<u>Final AAL = (0.2 mg/m³)/ (5.6 x 10 x 10) = 0.00036 mg/m³</u>	

The approach described above applies to chemicals that have AALs based on non-cancer health effects such as airway irritation or liver damage. They are believed to be without significant risk because they are set far below exposures associated with toxic effects. In the case of carcinogenic (cancer-causing) agents, risk assessment methods assume by default that no exposure is without at least some risk. In these cases, AALs are set at levels that represent extremely low incidence levels. For example, AAL guidelines for known carcinogens represent "one in a million" cancer risk. Using the assumptions outlined above, if one million persons were exposed to this level continuously, one person would develop cancer as a result of exposure to that chemical. The incidence guidelines for "probable" or "possible" human carcinogens are "one in one hundred thousand" and "one in ten thousand," respectively. These types of chemicals are known to cause cancer in laboratory rats and mice but have not been shown to cause cancer in people. Nevertheless, our risk guidelines dictate that we regulate them as if they do (DAQ, 1997).

What about multiple health effects? Some chemicals are known to cause multiple health effects in humans. For example, many solvents will cause lightheadedness following short-term (acute), high level exposures and organ damage following longer-term (chronic) exposure to lower levels. In these cases, multiple AAL guidelines may exist for the same chemical to control both acute and chronic exposures. When this is the case, short-term AALs act to "smooth out" emissions spikes while also regulating the total amount emitted over a longer period of time.

It is also worth noting that many of the long-term cancer based AALs are set at levels so low that they also become effective at reducing short-term exposures. This is especially true for manufacturing processes that tend to operate on a continuous basis. For example, the cancer

guideline for benzene is set at a level approximately 25,000 times lower than levels associated with non-cancerous outcomes (ACGIH, 1991).

How old are the AALs? Do they consider new information on health effects? On occasion, new scientific information will arise that suggests a chemical is more or less dangerous than previously thought. The toxics program keeps up with these changes by maintaining a Scientific Advisory Board (SAB) of toxicology experts that periodically suggest changes to AAL guidelines. The SAB is routinely called upon to address chemicals of concern. Risk assessments carried out by the SAB are handed over to the Division of Air Quality, which prepares them for introduction to the Environmental Management Commission (EMC) and the NC General Assembly. Under normal circumstances, this preparation process takes about three years. Under unusual, high priority circumstances, immediate measures can be taken to add or alter AALs in the regulations.

Examples of recently considered AALs include: Acrylamide, arsenic, benzene, MDI, mercury, methylene chloride, naphthalene, toluene diisocyanate (TDI), and vinyl acetate.

Does the Air Toxics Program Consider Pollutant Mixtures? Many pollutants will act together to produce greater, or in some cases less, toxicity to exposed individuals. Most toxicological data is available for single pollutants, making multiple pollutant risk assessment problematic. DAQ regulations will allow for consideration of multiple pollutant risk if there is "evidence that two or more toxic air pollutants being emitted from a facility or combination of facilities act in the same way to affect human health" (15 NCAC 2D .1108). In the past, DAQ staff have considered additive toxicity when considering the impact of multiple pollutants with similar effects (Milesen, 1996). These types of demonstrations may be used by the EMC to consider additional appropriate control measures.

If I can smell it, is it bad for me? Some pollutants have very strong odors and can be detected by people living near facilities, even if the emissions are being regulated under the air toxics program. This does not necessarily mean these exposures are dangerous. Hydrogen sulfide is an example of a chemical with a foul smell that can be detected at levels far below those thought to carry significant risk. However, other chemicals may be dangerous at concentrations lower than their odor detection levels. If odors from a nearby facility are constant or become aggravating, citizens should consider calling their regional Division of Air Quality office for further assistance.

What if I have more questions about the air toxics program? Many of the issues described above are very complex. We encourage citizens to call with any questions related to the structure and operation of the air toxics program. For more information please call Lori Cherry, Toxics Protection Branch Supervisor, at (919) 733-1476 or Jeff Hayward, Air Quality Toxicologist, at (919) 733-1475.

References:

- ACGIH (1991). Documentation for Benzene TLV-TWA.
- NCAS (1986). Report and Recommendations of the Air Toxics Panel of the North Carolina Academy of Sciences.
- Milesen, B (1996). DAQ Memorandum to Jerry Clayton; Multiple Pollutant Analysis, Carolina Solite Corporation.
- DAQ (1997). Secretary's Scientific Advisory Board on Toxic Air Pollutants (SAB) internal guidelines for toxicological evaluation of chemicals released to the air.