Dr. Michael Honeycutt (TCEQ) Responses to Questions from The Honorable John Shimkus

1. *You testified "EPA's new assessments will unnecessarily scare the public and may actually harm public health by diverting public, industry, and government attention and resources away from public health issues that pose more of a risk." Can you share with us more examples of industry and government action based on these values that have diverted resources?*

A perfect example is mercury. In their recent proposal to reduce emissions, specifically mercury, from power plants, EPA themselves determined that the rule will not have an effect on mercury levels in fish in America's watersheds. This rule will cost utilities, states, and the public (through higher energy costs) millions of dollars with little or no public health benefit. EPA continues to overstate the health risks of lower IQ and heart disease from mercury, while ignoring the very-well demonstrated health benefits of eating seafood. EPA used a study known as the Faroe Islands study to set their safe level for mercury, where the mothers ate whale meat and blubber contaminated with PCBs in addition to eating fish containing mercury. The Faroe Island infants ingested 600 times EPA's safe dose of PCBs in breast milk in addition to ingesting mercury. The effects EPA attributed to mercury could more justifiably be attributed to PCBs. A similar study in the Seychelle Islands that did not include PCB exposures was essentially negative. EPA ignores the fact that Japanese eat 10 times more fish than Americans do and have higher levels of mercury in their blood, but have lower rates of coronary heart disease and high scores on their IQ tests. Methyl mercury is a toxic chemical, but the scientific data overwhelmingly do not support EPA's position on the health risk of mercury. In fact, EPA may have the most conservative safe level for mercury in the world. The FDA, the ATSDR, the World Health Organization, and Canada have all set a higher safe level for mercury. Further, EPA still uses decade-old data when they say that 6% of the women in the US have unsafe levels of mercury in their blood. Newer data shows this isn't the case. Plus, the levels they say are "unsafe" are well below the levels shown to cause health effects. There are no widespread mercury health effects issues in the United States. In fact, unwarranted concerns about mercury may be causing women to avoid eating fish, which itself could lead to adverse health effects.

2. *You testified that EPA is moving toward a philosophy that there is no safe level of exposure to a chemical. And that includes naturally occurring chemicals? What does that mean, in practical terms?*

The philosophy that there is no safe level of exposure to a chemical means that any dose of a chemical, no matter how small, causes an adverse effect. This philosophy has typically been applied to carcinogens like arsenic, a naturally occurring chemical that can be found in soil and water. In practical terms, this means that an individual would have an increased risk of developing cancer

even if he/she were only exposed to a very low dose of arsenic. Based on EPA's most recent IRIS assessment of arsenic and available data from recent fish studies, all fish and shellfish would contain levels of arsenic that are higher than the highest levels EPA would consider safe. Normal dietary food and drinking water consumption would also contain levels of arsenic that would be substantially higher than the highest levels EPA would consider safe. We know these levels of arsenic are not unsafe because we are not seeing the increased cancer rates (and other health effects) in the general population that would occur if EPA's levels were realistic.

3. *What do you see as the key problems in EPA's IRIS assessments? Why are they important? Are these problems found in other science and health based agencies of the Federal government?*

Some key issues in EPA's IRIS assessments include: 1) they often don't follow their own guidance; 2) they ask for input from outside experts late in the process (after their minds are made up); 3 they allow very short time periods for public comment (e.g. 30 or 60 days to review a thousand page document is typical); 4) they tend to not finalize assessments when the science doesn't back up their position (e.g., the dioxin assessment has been draft for over two decades); 5) they are getting away from science-based assessments and going more towards precautionary policy-based assessments (e.g. when science demonstrates that a chemical is not as toxic as they think it should be, they ignore the science in favor of a policy decision); and 6) they don't do common-sense ground-truthing of their values (e.g., their unsafe levels for essential elements like copper are lower than what is recommended by the FDA).

Consistency, transparency, and the highest scientific integrity are paramount in regulatory decisions. If EPA consistently utilizes good science in their decisions, including in the IRIS program, then the motivation exists to develop good science. When EPA ignores good science which demonstrates that a chemical is not as toxic as they think it is, it creates an atmosphere of distrust, not to mention litigation. Developing "chicken little" toxicity values for chemicals - values that are below background levels or that (like copper) deem FDA recommendations as being unsafe – make the public either jaded or unnecessarily scared.

The TCEQ works more closely with and is more familiar with EPA policies and procedures, so I can't offer an opinion on other federal agencies.

4. *In your opinion, are there broader economic consequences associated with publishing an IRIS value that is lower than background levels? Will it impacts jobs and the economy?*

Yes. Such a risk assessment may have unintended consequences. Not only is it impossible to cleanup below background levels, costs in the daily lives of the public would be driven up from industry being forced to switch to alternatives (if available). While IRIS merely develops toxicity values, they have far reaching implications as they are used by regulatory agencies to make regulatory decisions. When a regulatory decision is made using a toxicity value that is extremely conservative, impacts are felt across the board. Not only does a company have to modify their process to accommodate use of a different chemical, which is expensive in itself, the cost is then transferred onto the public.

For example, IRIS toxicity factors are used to develop federal maximum contaminant level (MCLs) standards. States are required to use these standards to regulate levels of chemicals in public drinking water supply systems. The current arsenic MCL of 10 ppb is set at an "unacceptable" excess cancer risk level, according to the current IRIS toxicity values. However, arsenic is a naturally occurring constituent in soil and water and can naturally be present in water at levels above the MCL of 10 ppb, as is the case in different parts of the US, such as West Texas. As a result, public water systems may have to institute costly measures to treat the water in order to comply with federal regulations or pay costly fines for violating regulations. Costs are then passed on to the consumer. Also, many rural water systems serving relatively few customers over a large geographic area may be forced out of business due to the increased costs. This would require homeowners to drill their own private wells, which would likely not be regularly tested and treated like public water supplies.

5. *What is the value of a risk assessment value that identifies a level below background level?*

Achievement of acceptable risk, as defined by the EPA IRIS toxicity values, would be practically impossible at not only remediation sites, but also at residential homes as the toxicity value would imply that typical naturally-occurring levels of a chemical were unsafe for human contact. Such assessments are unnecessarily alarming to the public and only cause more harm than good (e.g., can cause stress in the public, are unnecessarily expensive, etc.). When an agency, which is looked to for development of the toxicity values used in risk assessments, begins routinely developing extremely conservative values that are below background, confidence in values that agency develops, and the agency itself, is diminished. Agency resources would then be focused on responding to the public or remediating sites to chemical levels that are overly conservative instead of being focused on real environmental risks and dangers. Limited federal and state resources should be focused where the greatest health benefit can be obtained.

6. *Is it standard practice for a risk assessment to produce a range of values, such as a high-end and low-end estimate of risk? Why is that important?*

It is typically not standard practice to develop a range of values for a chemical risk assessment. The one exception on the IRIS database is benzene, which does have a range of values. It is important to provide risk managers and policy makers adequate information to make informed decisions. Sufficient information would include limitations and confidence in the data used to develop the risk values, concentrations known to produce health effects, and the likelihood of exposure to the chemical.

7. *Is it true that a substance can be associated with risk at high levels, but be safe and even necessary for health at low levels? Can you share any examples? (Over-the-counter analgesics, or food supplements, for example?) Does this imply that risks assessed at high levels are not necessarily the same risks at lower levels?*

Yes, vitamins and essential nutrients can be associated with adverse health effects at high levels, but are necessary for health at lower levels. Examples include Vitamin A, iron, and selenium. High doses

of Vitamin A can cause liver toxicity and birth defects, high doses of selenium can affect the brain, and high doses of iron can cause liver toxicity and metabolic acidosis. Low doses of these substances are essential for life. This means that there is a risk of adverse health effects if not enough exposure occurs and a risk of adverse health effects if too much exposure occurs. For this reason, the effects of a chemical are not proportional, i.e., an effect at a higher dose cannot be assumed to indicate that a lower dose would have the same adverse effect.

8. Recently, a toxicologist Dr. Peter Valberg testified before the Energy and Power subcommittee that "The dose makes the poison". What does that mean, in assessing risk?

The phrase, "the dose makes the poison," is attributed to the 'father' of toxicology, Paracelsus (1493-1541). What he described was the dose-response concept and it is one of the fundamental ideas in assessing risk, in that, typically at higher doses the severity of an adverse effect increases. Even though some things are described as nontoxic, essentially everything, even naturally occurring chemicals, can be toxic at a high enough dose (e.g., water, caffeine, aspirin, sugar). For example, even water is toxic at a high enough dose. Water intoxication can cause disturbances in electrolyte balance, resulting in a rapid decrease in serum sodium concentration and eventual death.

Health-based standards are often based on maximum acceptable concentrations of a chemical, assuming that exposure to below that standard or threshold would be safe. However, as a precaution some chemicals for regulatory purposes are considered not to have a threshold (for example, some cancer-causing chemicals) and thus, risk assessment involves ensuring the dose-response of a chemical is properly characterized.

9. Is having something peer reviewed a sign of quality work?

Most often, yes, if the peer review process is conducted properly. Scientific work is self-monitored through peer review which provides an initial stamp of validity to other scientists and the public. Peer review should involve the thorough examination of a study or manuscript by other knowledgeable scientists in the field who can provide a critical analysis and review. Typically, most scientists will not consider a study valid unless it has been through a peer review process. Without it, results would be considered preliminary. The peer review process is not perfect. As much as possible, peers reviewing the work should have the appropriate expertise and not have conflicting interests. Ideally, peer reviewers and their comments should be publicly identified, though their comments do not necessarily have to be directly attributable to them. Also, the scientist doing the original work should make responses to the peer reviewer's comments public. Peer reviewers are not infallible and thus, may make mistakes or miss important deficits. However, a scientist knowing their study will be vetted through peer review, by itself, may make the study more rigorous than it would otherwise be without that process. In general, the process works by improving scientific work.

10. Does IRIS exaggerate risk? Why should we care?

Yes, IRIS exaggerates risk. All regulatory toxicity values exaggerate risk to some extent. Regulators (including me) have a penchant to err on the side of conservatism (health-protectiveness) when extrapolating potential health effects from animal studies or clinical/worker human studies to the general population. Developing toxicity values is a branched, multi-step process. At each intermediate step, if no scientific data is available, one can use policy-derived default values that are intentionally overly-conservative. At the end of the process, the various branches are multiplied (which compounds the conservatism) together to derive the toxicity factor. The problem with IRIS is that EPA tends to ignore scientific data that demonstrates the policy-derived default values are not appropriate. When this happens, the IRIS values are not just conservative they are not scientifically based.

A good example is EPA's most recent IRIS assessment for formaldehyde. Ample scientific data exist that clearly demonstrates that when living organisms inhale formaldehyde, it does not enter the blood stream and circulate to other parts of the body. It stays in the respiratory tract. However, EPA ignored this data and chose instead to rely on a single epidemiology study[1] that *did not* show a statistically significant association between formaldehyde and Hodgkin lymphoma and leukemia, but they used it anyhow. In order for formaldehyde to cause these diseases, it would have to enter the blood stream, but it clearly does not based on studies that examine whether or not inhaled formaldehyde is absorbed from the lungs and transferred throughout the body. As a result of assuming formaldehyde can cause Hodgkin lymphoma and leukemia, along with the compounded conservatism of the process, EPA's proposed formaldehyde toxicity value would mean that the formaldehyde in human breath that results from normal body functions would be over 5 times higher than the highest level that EPA would call safe.

This assessment will unnecessarily scare the general public. Formaldehyde is naturally formed in the air from the breakdown of chemicals released from vegetation. According to available air data, the only places that would have safe air would be remote locations such as the arctic or South Pacific islands.

11. *How useful do you find IRIS values when they are set to levels below background or lower than naturally occurring background levels? Can you please speak to the issues that have challenged your state in this area?*

IRIS values set to levels below background or lower than naturally occurring background levels are typically not useful. If a toxicity value derivation process comes up with such a value, it should be carefully examined to see how much confidence can be placed in the value; to put the value in context with levels where adverse effects are known to occur.

[1] Epidemiology studies are designed to show a correlational rather than causal relationship between exposure and effect. Epidemiology studies are useful in hazard identification, and if accompanied by accurate exposure data, may be useful in the dose-response assessment for a toxicant. Use of epidemiological studies may be limited by confounding factors (e.g., predisposing lifestyle factors, preexisting health problems), reliability of the exposure data, and lack of a causal relationship between exposure and effect.

Since these new toxicity values (formaldehyde, arsenic, hexavalent chromium, etc.) are draft, Texas has not yet felt an impact. However, because these draft values are overly conservative, we are anticipating the need to develop our own toxicity values for these chemicals to use in our soil remediation program. Unfortunately, should Texas develop more scientifically rigorous values that are higher than EPA's value, the public might not think we are being health-protective. Further, developing state values where the EPA has already created toxicity values is a diversion of resources that could be focused elsewhere.

Dr. Michael Honeycutt (TCEQ) Responses to Questions from The Honorable Joe Barton

1. *How do you establish your priorities? (In other words, what chemicals do you study first and fore-most) Do you have a criteria set forth in a policy format?*

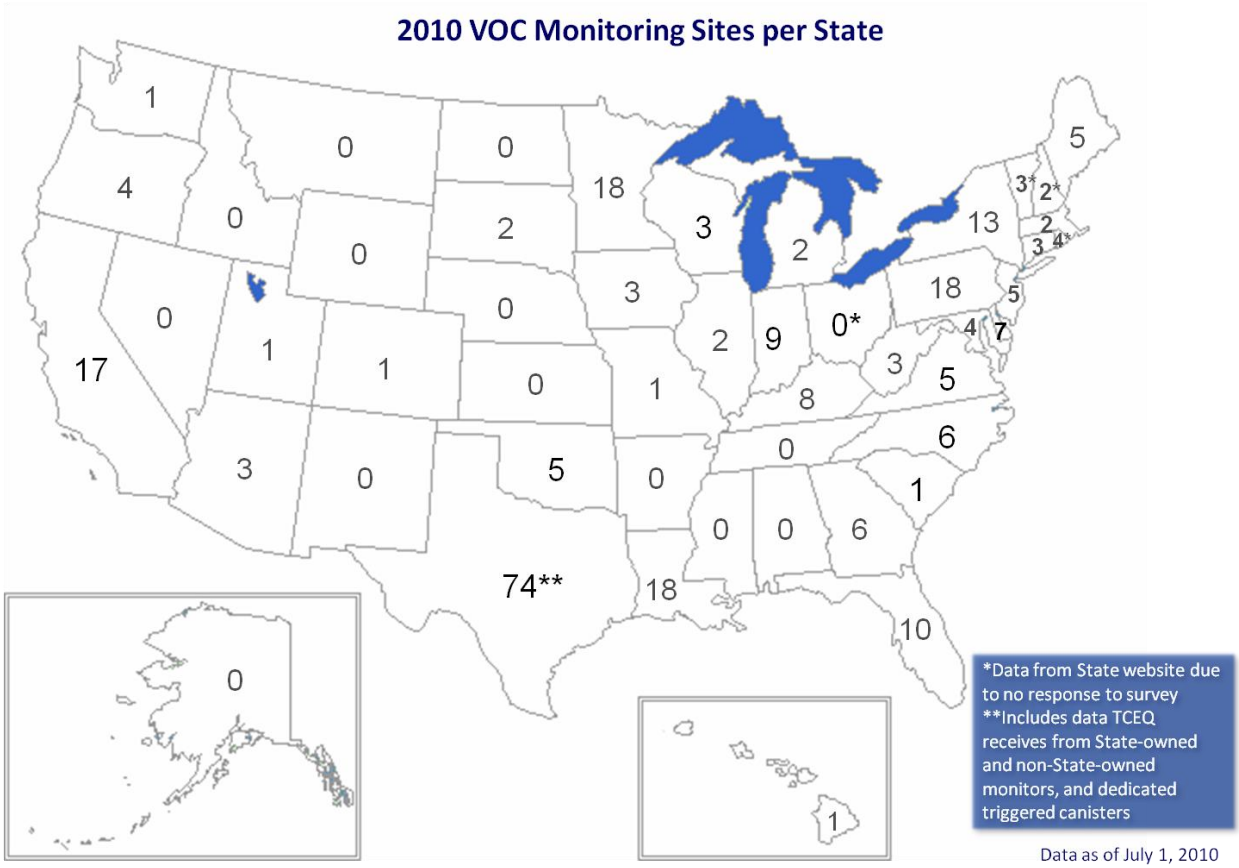
Chemicals are studied in order to develop toxicity factors and screening levels used in TCEQ air monitoring, air permitting, and remediation programs. Chemicals are prioritized based on a number of factors including whether they have been detected in ambient air monitoring, whether TCEQ frequently issues permits for them, whether they have been detected in soil and/or water sampling associated with remediation activities, and if the public has expressed concerns about them. These criteria are specified in the TCEQ Toxicology Division's DRAFT 2011 "Guidelines to Develop Inhalation and Oral Cancer and Non-Cancer Toxicity Factors." (http://www.tceq.texas.gov/toxicology/esl/guidelines/about.html)

2. *What analytical systems do you utilize to determine the potential risks to a population? Do you have a standardized system?*

The state of Texas currently conducts routine ambient monitoring of air and water, which is analyzed using EPA-approved methodologies. Soil is sampled and analyzed as needed (e.g., remediation sites, complaints from citizens, field investigations) also using EPA-approved methodologies and typically evaluated using the Texas Risk Reduction Program (TRRP) Protective Concentration Levels (PCLs), which are cleanup levels set to protect public health from a long-term direct exposure perspective.

There are federal standards for drinking water and state standards set (as approved by EPA) for surface water quality. The TCEQ Office of Water has several water programs and routinely evaluates the waters of the state for compliance with water quality standards.

For ambient air, federal standards exist for six criteria pollutants. For all other chemicals emitted in the state of Texas, we have developed screening levels. The TCEQ routinely monitors ambient air via stationary monitoring, mobile monitoring and field investigations. The TCEQ has the most extensive ambient air toxics monitoring network in the country, monitoring for more than 120 chemicals across the state (see figure below). The TCEQ monitors for compliance with criteria air pollutants and routinely evaluates air toxics data across the state. If a potential issue with ambient air is identified, the chemical and area are highlighted on the Agency's Air Pollutant Watch List (referred to as the APWL). This list serves as a tool for the Agency to focus resources on correcting potential issues.



3. What external agencies do you gain your knowledge base from on exposures to chemicals? AMA/ACS/NAS etc?

The TCEQ refers to numerous sources for toxicity and exposure information on chemicals. Initially, because of time and resource constraints, published toxicity values and/or data developed by another federal or state agency are evaluated. When a toxicity factor or guideline level is identified in the scientific literature or in a database, it is reviewed to determine whether the approach used to develop the factor is similar to the procedures used by the TCEQ to develop its toxicity factors. If so, the TCEQ may adopt the published toxicity factor or guideline level, with preference given to values that have undergone an external peer review and public involvement process. However, because more recent information may be available, the TCEQ also evaluates peer-reviewed scientific studies available after the published date of the toxicity factor or guideline level to ensure the latest data are considered. Specific external agencies the TCEQ frequently cite include the Agency for Toxic Substances and Disease Registry (ATSDR), EPA, California EPA, National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances, DOE, OSHA, ACGIH, CDC, WHO, and other international organizations.

4. Please explain a step by step process by which you go about evaluation of a particular chemical.

TCEQ has developed a state-of-the-science, peer-reviewed process for developing toxicity values for chemicals. When a chemical undergoes this evaluation a development support document (DSD) is

created. The DSD provides a summary of information on the development process and the key toxicity information upon which the toxicity values are based. The first step in this process is to conduct an exhaustive review of the available scientific literature and solicit information from interested parties. Once the literature review is completed, there are two main types of toxicity values developed; acute (short-term) and chronic (long-term), which protect against short- and long-term exposures, respectively.

For development of an acute toxicity value, the first step is to determine if there is enough acute toxicity data available to develop a toxicity value. If there isn't sufficient data available, a default or generic health-based toxicity value will be developed using conservative procedures as specified in the TCEQ Toxicology Division's DRAFT 2011 "Guidelines to Develop Inhalation and Oral Cancer and Non-Cancer Toxicity Factors." Otherwise, the next step involves analyzing the collected literature to determine how the chemical produces toxic effects in the body (i.e., mode of action (MOA)). Once the MOA is determined, an acute toxicity value is developed. After developing an acute health-based toxicity value, welfare-based (i.e., odor and vegetation) toxicity values are developed (if necessary).

For development of a chronic toxicity value, the next step involves determining if enough chronic data is available to develop a cancer-based and/or a non-cancer based chronic toxicity value. If there isn't sufficient data available, a generic health-based toxicity value may be developed. Otherwise, the chronic literature is then evaluated to determine the chronic MOA (if different from the acute MOA). As with the acute toxicity values, once the MOA is determined a chronic carcinogenic toxicity value is developed (if appropriate). If data is available to support a non-carcinogenic MOA, the next step is to develop a chronic non-carcinogenic toxicity value. After developing the chronic health-based toxicity value(s), a welfare-based (i.e., vegetation) toxicity value is developed (if necessary).

Once toxicity factors are initially developed, they go through a rigorous internal review for scientific consensus within the TCEQ Toxicology Division. After that, the toxicity factors are considered proposed, high profile chemicals may undergo a peer-review at this point and all DSDs undergo a 90-day public review and comment period. For data-rich or controversial substances, additional time may be allowed for the review and comment period. After the review and comment period ends, the comments are addressed and resolved, the document undergoes another round of internal review for consensus and the document is then finalized with responses to the received comments.