Memo

To: Technical Workgroup
From: DEQ and OHA
Date: June 14, 2016
Subject: Setting and Administering Acceptable Risk Levels (UPDATED 7/28/16)

Introduction

The Cleaner Air Oregon rulemaking is a partnership between Oregon Health Authority and Oregon Department of Environmental Quality to develop a new regulatory system for managing air toxics emissions from industrial sources. The new rules will be based on the potential risk to human health so DEQ can carry out its mission of cleaner air and a healthier Oregon. In developing this new regulatory approach, the two agencies will begin looking at individual sources of industrial emissions across the state in relation to public health benchmarks.

DEQ and OHA have evaluated other state air toxics permitting programs and narrowed the field to six programs for further assessment: Louisville, Kentucky; New Jersey, New York, Rhode Island, South Coast Air Quality Management District (California), and Washington. Key elements of these air toxics programs will be summarized and presented to the Technical Workgroup and the resulting policy issues will be discussed at Policy Forums around the state and with the Advisory Committee. After receiving input on the different aspects of a risk-based air toxics permitting program from the Technical Workgroup, the Policy Forums, and the Advisory Committee, DEQ/OHA will draft proposed rules and all interested parties will have a chance to comment on the proposed rules during the public notice period in 2017.

DEQ and OHA will be updating this issue paper throughout the rulemaking process based on input from the Technical Workgroup, Policy Forums around the state and the Advisory Committee.

A glossary of terms can be found at this link: https://www.oregon.gov/deq/RulesandRegulations/Advisory/8Glossary.pdf

Purpose

This issue paper addresses the key element of setting and administering acceptable risk levels. How have other states defined the acceptable level of risk? How do other states account for pollutants from other sources?

Acceptable Risk Levels

How have other programs defined the acceptable level of risk?

State and local regulatory agencies evaluated generally start at a one in one million risk level for carcinogenic contaminants and a hazard quotient of 1 for non-carcinogenic contaminants as an initial screening step. Most states have a provision for higher levels of risk if facilities have demonstrated that they are using the best available control technology to control air toxics and further risk reductions are not possible.

Program	Program Description
Louisville, Kentucky	Initial screen Screening level starts with one in one million cancer risk and a hazard quotient of 1. If initial screen indicates higher risk, a more refined risk assessment is done to determine whether emissions pose an actual risk to public health. Adjustments for roadways and industrial properties allowed. More refined risk assessment Cancer risk goal for a single contaminant for a single piece of new equipment is one in one million or a hazard quotient of 1. The cumulative risk goal for multiple carcinogenic contaminants for a new source is 3.8 in one million. The cumulative risk goal for multiple carcinogenic contaminants from an existing source is 7.5 in one million. Sources that cannot meet the goal must implement T-BACT or "best available control technology for toxics" and apply for a modification or implement a Risk Reduction Plan developed by the District. There is no guidance on cumulative risk from multiple contaminants for non-cancer risk. No individual contaminant can have a hazard quotient greater than 1.
New Jersey	Total incremental risk less than or equal to one in one million is considered negligible. If Incremental Cancer Risk is between one in one million and 100 in one million, case by case review by Risk Management Committee is required. The permit may be issued if risk is acceptably minimized. If Incremental Cancer Risk is greater than or equal to 100 in one million, (unacceptable risk), the permit will not be approved. A hazard quotient less than or equal to 1 is considered negligible. A hazard quotient greater than 1 requires review on a case-by-case basis by the Risk Management Committee.
New York	Risk-based concentrations for carcinogens are set at the one in one million risk level and a hazard quotient of 1 for individual contaminants for screening-level analysis. If initial screening is failed, then T-BACT analysis and application are used. If screening still fails, then 10 in one million cumulative cancer risk or hazard index of 2 is acceptable.
Rhode Island	Acceptable risk is set within the range of one in one million to 10 in one million cancer risk. Non-cancer acceptable risk is a hazard quotient less than 1.
South Coast Air Quality Management District (CA)	New or modified sources

Program	Program Description
	Cumulative cancer risk from a single piece of equipment cannot exceed one in one million if T-BACT is not in place. 10 in one million is acceptable if T-BACT is in used (applies only to new or modified equipment). Organ-specific hazard index (cumulative risk for non-carcinogens that affect same organ or system) cannot exceed 1 (applies only to new or modified equipment). Existing sources Cumulative "action risk levels" for an entire facility are 25 in one million cancer risk, and no organ-specific hazard index can exceed 3. "Significant risk levels" are 100 in one million cumulative risk for entire facility or an organ-specific hazard index of 5. Public notification requirements on existing sources are triggered at 10 in one million cancer risk or an organ-specific hazard index of 1.
Washington	**Tier 1 – Screening**. Emissions (or modeled concentrations) of each regulated toxic air pollutant are compared to respective Small Quantity Emission Rate or Acceptable Source Impact Level. Each Acceptable Source Impact Level based on cancer effects is set at a lifetime increased risk level of one in one million (annual averaging time). For non-cancer hazards, no individual contaminant can have a hazard quotient greater than 1 (based on 24-hr average or less), If any pollutant exceeds an Acceptable Source Impact Level, then a Tier 2 (health impact assessment) is required. **Tier 2 – Health Impact Assessment** – although a single pollutant may trigger second tier review, Ecology considers the cumulative cancer risk of all emitted pollutants from the new source or modification. This additive risk cannot exceed 10 in one million. For non-carcinogens, the agency has more flexibility about which non-cancer risk-based concentrations and averaging times to use. The rule does not specify an acceptable non-cancer hazard quotient or index. This decision is left to the discretion of Ecology. **Tier 3 – Risk Management Decision** is essentially a repeat of Tier 2, but applicants can attempt to demonstrate that the benefits of their facility's activities outweigh the modeled risks, and the director of Ecology makes the final decision. A mandatory public meeting is required under Tier 3.

The following information was gathered at the June 30, 2016 Technical Workgroup meeting:

Pros and Cons of acceptable risk levels:

- EPA has a range of acceptable risk, 1 and 100 in 1 million is a "grey" zone, where the technology is taken into account. How many people exposed, cost of controls all taken into account. This grey range is where pollution prevention and green chemistry are really working to change what we do. Many people don't believe T-BACT is enough. What we need to do is build incentives for making changes in this grey zone which could induce the numbers back down.

- SCAQMD says if you are under 1 in 1 million, then you don't have to use T-BACT. Sources that install T-BACT get to use a different threshold. Different thresholds are not used in WA. As you ramp up, the levels get more stringent.
- On the implementation side of a risk assessment, it's fairly easy to get to 1 in 1 million but harder to get to 10 in 1 million. A lot of risk assessments fall in between 1 and 10. It's also surprising how many risk assessments come in a 9.9 in 1 million.
- Be consistent. Other DEQ programs use 1 in 1 million. That should be taken as your baseline. You might need a higher risk level for existing sources as SCAQMD did (100 in 1 million).
- The levels of acceptable risk depend what you are going to do with it. Permitting decision for new units? For existing sources, use a facility wide threshold? Public notification requirement could also be a different level. Need to look at how much conservatism is built into your methods (i.e., modeling and emissions estimates)
- Using two different levels for screening and refined analysis can be very dangerous. There is more certainty in monitoring than modeling. Generally, when one is doing a risk assessment, more than 1 significant figure is not used because there is a lot of uncertainty in the numbers. Be careful if you have different benchmarks and use them in the appropriate situation.
- One downside is basing risk on only one facility's emissions. If you have lots of similar facilities in the same area, there could be a higher risk. You may build in safety factors in the emission rates to account for this scenario.
- DEQ and OHA have not decided yet on whether they will rely on other agencies for establishing risk levels. Most states rely on a few agencies that have resources to do this work.
- Assessments take time. On the risk communication side – what about the chemicals that you do not have information on? Use the best science you have at the time.
- ATSAC looks at IRIS, OEHHA or ATSDR (Agency for Toxic Substances and Disease Registry) values. For diesel particulate, ATSAC is doing own its review of primary literature. What if the new chemical does not have a toxicity value established by agencies in hierarchy? This is more common for short term values. In risk communication, the public may ask about this compound you didn't evaluate. You may need to say "I have nothing to compare it to." Use the best information you have at the time.
- DEQ and OHA should select a likely surrogate for chemicals without benchmarks where the chemistry is similar to different chemicals using methods such as QSAR or read-across.
- DEQ and OHA should look at maximum individual risk and population risk using census blocks. There are around 8 million people exposed to risk from refineries. EPA looked at demographic information and about half the population lives in EJ communities. They were able to reduce risk from 8 in 1 million to 4 or 5 in 1 million.
- When looking at risk, how do they change over time? If we have infill, how do you take that into account? It can be difficult when environmental regulators come in after zoning decisions have been made. Zoning shouldn't allow heavy industry near residential areas. While we can minimize risk, we cannot change zoning. One thing that has been useful in California is their land use handbook guidance on how to consider land use and how close is too close. Most city planners don't know air quality but they have understanding planning and use this handbook. SCAQMD also has good guidance on locating schools. DEQ and OHA should develop guidance on where people should live. Questions from the public include "Should I move here?" It comes down to a zoning problem.

- The public asks about cumulative risk. What are other environmental risks in the ground water and subsurface contamination? What about cumulative risks through time for new regulatory programs but people and sources have been here for 40 years. Are we still letting them do something in the future? Cumulative risk has many definitions. Mainly we look at air pathways only but you can look at multiple pathways, such as concentrations in soil, drinking water, and bioaccumulations in organisms.

The following information was gathered at the June 30, 2016 Technical Workgroup meeting:

Pros/Cons for higher levels of risk for T-BACT:

- Washington permits both criteria pollutants and air toxics. 99.9 times out of 100, BACT is same for criteria pollutants and air toxics, except for mercury. They don't have different cost effectiveness thresholds used for toxics. BACT is required for any emission increase; it is not the same in Oregon. T-BACT may not always reduce risk enough to provide justifiable benefit.
- T-BACT is ultimately an emission limit that goes into permit for the technology that is proven and affordable. The economic situation also determines BACT. Lowest Achievable Emission Rate (LAER) is typically required in nonattainment areas, of which there are none in Washington.
- When the risk is between 1 and 100 in 1 million, there is a great opportunity for facilities to get creative. Pollution prevention or green chemistry are working to see how to lower risks. Many people believe BACT is not enough for criteria pollutants or toxics. This is the place to build in incentives to change the way production happens to reduce numbers.
- There is an advantage in Oregon because of cyclic process to look at permits at renewal. Dialogue with facilities that want to be good citizens can include how they can reduce risk. There can be inexpensive fixes because BACT allows for creativity.
- EPA reviews MACT standards every 8 years to see if new technology is out there and adds on to regulation. BACT also evolves so it might be helpful to get more engineering expertise.

The following information was gathered at the June 30, 2016 Technical Workgroup meeting:

Pros/Cons of unacceptable risk:

- There is a public concern that no level of risk is acceptable. Risk assessments are uncertain. We want to be protective as possible.
- Is there a number such as 1 in 1 million, where you don't get a permit?
- Need to consider multi-pathway concerns, population at risk, etc. Inhalation RfC is different than ingestion. EPA has a range of 1-100 in 1 million, where above 100 is in a million is unacceptable.
- SCAQMD does not take population into account. Does have a cancer burden for population, which is sometimes triggered. Does take into account current zoning (future land use. For example, zoned residential even if no one lives there yet).
- SCAAQMD has a hard bright line of 10 in 1 million as acceptable risk. There is an appeal process to the hearings board but they are very rarely granted. Exemptions are built into rules for some equipment on the permitting side because of small sources. There are hard thresholds on existing equipment. DEQ and OHA need to determine whether to use existing thresholds. What is the impact of 10 in 1 million on the public, business, and agency resources? The best utility of risk assessment is when it's used in a standard method across

the board; all risk assessments are done in this method. Exact number might have a lot of uncertainty but when comparing them to other facilities, there is a lot more certainty when using a standard method.

- DEQ and OHA should be careful when setting a hard line. Risk assessment is an art so trying to get it right is like forecasting weather. It depends on the certainty you have in the number against which you are comparing it. It also depends on actual or potential emissions. One needs to do a case-by-case determination on any type of application. It comes down to economic decisions too. Do you want to drive industry out of the country?
- Non-cancer hazard quotients are not created equally. Some non-cancer risk-based concentrations have greater margins of safety (i.e., more uncertainty factors) built in so you can go to a higher level. Just because you are over 1, doesn't mean you will have health effects. The hazard quotient of 1 is a safety level. The further you get away from that line, the more likely you will have adverse effects.
- Washington does not have a non-cancer hazard quotient in rules. They do not define a threshold so it's a case-by-case decision. There are cases where facilities get a permit with a hazard quotient greater than 1 but the likelihood of short term exposure is low. Wood products facilities sometimes have impact levels above reference concentrations. The decision about granting a permit when non-cancer risk is above a hazard quotient of 1 is at the discretion of the toxicologist with input from risk managers.
- SCAQMD has a bright line threshold of 1 for non-cancer. In California, lead is considered carcinogenic. Lead is unique in that the CDC has recognized that there is no safe level of lead exposure, so exposures of any magnitude could pose risk. Use NAAQS as the risk-based concentration for lead.

The following information was gathered at the June 30, 2016 Technical Workgroup meeting:

Pros/Cons of different acceptable risk levels for new and existing sources:

- Washington's rule is specific to New Source Review. It turns a blind eye to risks from existing sources. Background is mentioned in risk assessment but it's not clear as to what is considered in background. An individual facility cannot be greater than 10 in 1 million. If you look at existing sources, do you look at facility wide impacts? Cumulative risk for all facilities in area? If you look at all risk from all facilities and mobile sources, it's hard to draw a line.
- South Coast uses 10 in 1 million with BACT on a permit unit basis for New Source Review, not the entire facility. When looking at existing sources, SCAQMD looks at the entire facility, all permitted and unpermitted units at facility. 10 in 1 million requires public notification. 25 in 1 million requires sources to conduct risk reduction. The California Environmental Quality Act requires cumulative impacts and broader understanding of environmental impacts, permitting, and land use. Other tools are used to focus on certain areas.
- It can be dangerous to have different levels for new and existing units. This can be handled on implementation. You can give existing units more time to comply where new units need to comply immediately. Creativity comes in for existing facility implementation. Sources can buy more land as a buffer zone to make sure they can restrict land from future development.

What are the advantages of these approaches to acceptable risk?

Program	Program Description
Louisville, Kentucky	*DEQ and OHA are seeking technical workgroup input on the advantages of Louisville's approach to acceptable risk.*
New Jersey	This approach is flexible and allows for consideration of technical feasibility and unique site characteristics
New York	*DEQ and OHA are seeking technical workgroup input on the advantages of New York's approach to acceptable risk.*
Rhode Island	*DEQ and OHA are seeking technical workgroup input on the advantages of Rhode Island's approach to acceptable risk.*
South Coast Air Quality Management District (CA)	Provides South Coast with flexible range of acceptable risk with various actions triggered at different risk levels.
Washington	This approach allows for rapid screening in Tier 1 assessments with very conservative, health protective assumptions, and greater flexibility for the agency in addressing those applicants that choose to move forward with a Tier 2 assessment.

TECHNICAL WORKGROUP QUESTION: What are the advantages of the different state and local agency regulatory approaches to acceptable risk?

What are the challenges of these approaches to acceptable risk?

Program	Program Description
Louisville, Kentucky	These levels of risk from a point source may be very difficult to achieve for some contaminants because additional sources other than point sources (cars, trucks, wood burning, etc.) also contribute ambient background concentrations for many air toxics in many areas.
New Jersey	There is no absolute risk number that is used as a result of the flexible approach.
New York	These levels of risk may be very difficult to achieve for some contaminants, especially if background is considered and the contaminant has other sources

Program	Program Description
	besides industrial stationary sources. Initial screen does not consider cumulative risk across contaminants, although second screen (post T-BACT) does consider cumulative risk.
Rhode Island	Allows facilities with risk greater than one in one million to be permitted and operate at that risk level.
South Coast Air Quality Management District (CA)	System is somewhat complex and requires guidance from South Coast in order for regulated community to understand how to comply.
Washington	The practice of 24-hour averaging times compared against chronic toxicity values for non-carcinogenic compounds is potentially overly conservative and may screen facilities into the Tier 2 process when it may not really be necessary.

TECHNICAL WORKGROUP QUESTION: What are the disadvantages of the different state and local agency regulatory approaches to acceptable risk?

Risks from Multiple Sources

How do other programs account for pollutants from other sources, including background? What are the advantages/disadvantages of their approaches?

How are other programs addressing cumulative risk, whether from multiple chemicals or from multiple sources? What are the advantages and disadvantages of their approaches? Do their programs address nearby industry or other emission sources such as roadways and burning?

a. How is modeling risk for cumulative sources triggered in their approach? (Is it triggered for both cancer risk and non-cancer hazard?)

b. Is risk from several pollutants considered or a single pollutant from several sources? (Is it considered for both cancer risk and non-cancer hazard?)

c. Does the program consider airshed, or background, risk? If so, how do they approach it, and what are the pros and cons? (Is it considered for both cancer risk and non-cancer hazard?)

d. Do the other programs address ecological risk or secondary effects such as crop damage?

Risks related to the emissions of multiple chemicals, or to emissions of chemicals from multiple sources, are commonly discussed as cumulative risk. Air programs with risk based permitting have all needed to define what is meant by cumulative risk, and whether or not the program will include the consideration of ambient air toxics concentrations not emitted by the permitted facilities.

The terms “cumulative risk” and also “aggregate risks,” within the context of air quality assessment of cancer risks and non-cancer hazards, are used in different ways by different programs. For the purposes of this discussion, the term “risk” will be used to represent both cancer risks and non-cancer hazards. In some cases, “cumulative” risk refers to the sum of risks from multiple chemicals coming from a single source, while “aggregate” risk tends to refer to the sum of risks coming from multiple sources (e.g., facilities). In other cases, the term “cumulative risks” can refer to the sum of risks from multiple chemicals emitted by a single source, or to the sum of risks being emitted from multiple sources within an area or region. In some cases, ambient concentrations of air toxics not emitted by the permitted facilities may also be considered in the assessment of cumulative air risks.

All six state and local programs utilize some form of tiered health-based approach. Typically, if cumulative health risks are addressed, it is during the second or third step (tier) of the health-based approach, which involves the preparation of some form of a human health risk assessment.

Under the Louisville program, a source that cannot meet the environmental acceptability goals may request a modification. The request to modify an Environmental Acceptability goal must include an evaluation of costs, technical feasibility, and relevant (including current and up to 25 years in the future) demographic and land use factors. Relevant factors include the frequency and duration of public access to the area where the Environmental Acceptability goal is exceeded; the nature, type, and use of the area; and how each relevant factor may change over the 25-year period. In evaluating future changes, available land use, population, and transportation horizon projections shall be included. The evaluation may include the results of an EPA-approved human exposure model and any other relevant factors. As an alternative, the source may be required to implement a District-developed Risk Reduction Plan.

Some state programs require or allow the assessment of multiple pathways risks, which means that exposure to a chemical through more than one exposure pathway is quantified, and the multiple pathway results are looked at in total to make decisions about whether or not adverse cancer risks or non-cancer hazards are occurring.

The following information was gathered at the July 27, 2016 Technical Workgroup meeting:

Pros and Cons of adjusting Risk Based Concentrations for cross-media exposure pathways:

- If Washington could do it over again they would include persistence and bioaccumulative factors in the list of pollutants. Now they only look at inhalation during the initial screening step but consider other ways of exposure during subsequent tiers of analysis.
- It can be difficult to address other media without this expertise. The Washington State Environmental Policy Act requires applicants to tell what they are doing and how will it affect all aspects of environment. This document is circulated to agencies around state to help inform others about multimedia impacts.
- Environmental justice says there are cumulative exposures that should be considered in different ways because of different exposure pathways such as groundwater pollution, soil gas pollution, and air pollution. In CA, different media are governed by different agencies so it’s hard to look at cumulative risk from different pathways. You can look at cumulative risk through time by doing risk assessments with best information available at the time. Historical exposure is real to the population but it’s difficult to quantify what those impacts are. Sometimes you just have to acknowledge there are previous exposures that we don’t know how to quantify.
- DEQ/OHA can’t use a fudge factor to address multipathway exposure. Some kind of trigger is needed to require a broader risk assessment rather than adding fudge factors to inhalation risk based concentrations to account for cross-media exposure pathways.

- Total Risk Integrated Methodology (TRIM) is EPA's model that evaluates multimedia chemical fate, transport, exposure and risk. It establishes de minimus emission levels based on inhalation, consumption, etc.
- South Coast performs a full multipathway assessment every time a risk assessment is done for new or existing sources. The Hotspots Analysis and Reporting Program (HARP) is a software suite used to assist with the programmatic requirements of the Air Toxics "Hot Spots" Program (AB 2588). HARP combines the tools needed to implement the requirements of AB 2588, such as reporting a facilities emissions inventory, determining a facilities prioritization score, conducting air dispersion modeling, and performing a facility health risk assessment.
- How do you take retrospective risk into account? Through litigation and looking at responsible parties to see how much do you assign to each facility? Litigation is not best way but has developed some sophisticated analyses which can help.
- For retrospective risk, it is– difficult to cover 20-30 years ago. One thing you can do in a risk assessment is to cover retrospective risk in the uncertainty section.
- Academic longitudinal epidemiological studies are used to inform the regulatory approach and risk assessments in CA. There is not a direct connection to permitting. These involve following what people's actual exposures were. These require a lot of research and resources.
- Pollution prevention looks at getting rid of silos and looks at cross media. In the toxic soup, there are so many other factors, such as the food we eat and the water that was used to grow the food. When you look at single facility, 1 in 10,000 is really 100 in 1 million, which is a pretty high number.

Some state programs direct the facility that is being regulated to sum the cancer risks and/or non-cancer hazards from multiple chemicals emitted from a single source or from multiple sources within a particular area or region, and to base decisions on health effect risks and hazards on both the risks from single chemicals and from multiple chemicals.

The following information was gathered at the July 27, 2016 Technical Workgroup meeting:

Pros and Cons of assessing cumulative risks related to multiple pollutants:

- All South Coast risk assessments look at all toxics identified and don't look at a single pollutant unless that is only one emitted. There are concerns when you look at multiple pollutants because the risk assessments typically don't address whether the chemicals interact with each other. What are the synergistic affects? What are the antagonistic effects (where chemicals cancel each other?) There isn't much data on this because the science isn't there yet. Pollutants are looked at one by one then summed.
- AB 2588 deals with existing sources that report every 4 years. Health risk assessments are based on actual emissions (not permitted) if they meet triggers. Sources may need to do HRAs for multiple calendar years. These periodic snapshots don't add up completely but show how things change overtime, whether risk is going up or down. It takes time to build up a database.
- At EPA they add carcinogens together because people don't breathe individual pollutants. For non-cancer effects, EPA has target-organ specific hazard indices (TOSHI) for some pollutants. The approach for cancer and non-cancer risk is very different. One molecule of a pollutant increases risk of getting cancer with increased exposure. For non-cancer effects, this is different than cancer risk because there are levels below which there is no measureable impact. EPA looks

at exposures for 70 years for cancer effects and 20-30 years for non-cancer effects, the porch potato approach, to be health protective.

- From a toxicological perspective, it makes the most sense to focus on respiratory or chronic effects on organs.
- Washington missed out by not summing risks for screening concentrations. Screening concentrations are set at 1 in 1million but if the facility has 20 carcinogens and all fall below screening level, the summation could be above the level of acceptability. When you screen by pollutant, you need to sum them and not look at them individually.
- SWCAA looks at all pollutants from a new facility and does not sum risk but conservatism is built into the numbers.
- In CA, risk assessment for non-cancer risks is done differently than for cancer risks. One molecule causes an unknown amount of cancer risk but it increases linearly. Non-cancer risk takes a different approach. The level for exposure is believed to not cause cancer effect. Lead is one pollutant that has well recognized non-cancer effects. One molecule of lead can have non-cancer effect. There are no safe exposure levels for lead so you can't do the cumulative assessment with lead that you can do with other pollutants. There are hazard indices for all other pollutants but for lead, they look at the national ambient air quality standards. There was a good health study done for lead with the NAAQS development.

Pros and Cons of assessing multiple pollutants from multiple sources within an area:

- In Washington, the rule specifies that other sources of toxics air pollutants in area must be considered. There are three choices:

    1. Using a modeling approach by looking at sources that emit that pollutant in 1.5 mile radius.
    2. Using the NATA census block.
    3. Doing monitoring, which they have never seen.

  How the final decision in issuing a permit is influenced by cumulative concentration is not specified in the rule so it causes confusion. The rule only specifies what the cumulative concentrations should be when doing modeling from commercial and industrial sources. Traffic pollutants may be biggest concern in an area. Oregon may want to consider background concentrations from non-stationary sources.
- When you try to model everything within a certain distance, you really need a good inventory. If you look outside the facility, you need to build that into the threshold value. Monitoring data is excellent but it is few and far between, very costly and takes time. Some states use highest monitored value as background but toxics are a very local issue. There is a lot of uncertainty in this so you should build it into the threshold value rather than trying to model all sources.
- South Coast treats cumulative risk different for new and existing sources. AQMD has done a study similar to NATA called Multiple Air Toxics Exposure Study (MATES). They put more local monitoring data and more refined emission estimates into MATES. The average risk is 900 in 1 million on cancer risk. The data is used as an informational tool, not a permitting tool. For new sources, they don't look at cumulative risk except as required by the California Environmental Quality Act (CEQA). For the port complex and refineries, if you put a benzene monitor in the area, how do you tease out where the benzene is coming from? Fugitive emissions are definitely a concern because they are hard to quantify. You need a good emissions inventory

to do modeling but it's incredibly difficult for fugitive emissions. Best way to address fugitives is through monitoring. You can use both modeling and monitoring to get to fugitive emissions and to craft mitigation and reduce pollutant exposures.

- You need an intricate monitoring system if you are looking at pollutants emitted from mobile sources but you need to be careful that you aren't double counting. If you look at a single piece of equipment, you are really slicing and dicing things. If you are looking at an air toxics program, you need to look at all pollutants from all equipment and the facility as a whole. Industry appreciates having flexibility to control another area that could cause larger environmental benefit.
- WA looks at individual pieces of equipment but also looks at the sum of those emissions from pieces of equipment when making a decision. If an existing facility modifies only one piece of equipment, then they look at just that one. For a new facility, they look at all the equipment and add the risk together by compound for screening. If required to go beyond the screening approach, then they sum the risks from compounds and equipment.
- Existing permitting is built on criteria pollutants. As you build air toxics rules, think about the monitoring data, which is much less for air toxics versus criteria pollutants.
- For SCAQMD, permits are equipment based and that's how the thresholds apply. Existing sources must look at facility wide emissions minus motor vehicles. When thinking about a single pollutant approach on a single piece of equipment, there are some pollution control technologies that create pollutants, like combustion or selective catalytic reduction, so there might be a tradeoff of one pollutant for another.

By rule, the New York program must protect both human health and the environment. The Louisville STAR program protects the environment in the evaluation of T-BACT, which is required for approval of a modification. The other four programs seem to focus only on protection of human health.

The Washington program requires, in the second tier of their risk-based program, that background concentrations of toxics in ambient air be considered along with assessment of potential risks and hazards related to facility emissions. Recent additions to the New York rules require that the National Air Toxics Assessment data will be used to identify background risks and hazards associated with ambient air, and considered along with potential risks and hazards related to facility emissions.

The following information was gathered at the July 27, 2016 Technical Workgroup meeting:

Pros and Cons of including background/ambient concentrations in the assessment of risk:

- The cost of some air monitors is really dropping. As monitors become consumer products rather than just technical equipment, average citizens use them but how does an agency use that data? Think about what you will do with that data.
- Technology is evolving quickly. For refineries, they are using tubes placed out in the field on fence posts or telephone pole so don't need fencing to protect the monitor. The problem with the tubes is that is not real time data, which is what the community wants. There are apps on phones that can measure pollutants and how do you upload data? How do you QA/QC data? The weather industry went through a similar trend with people having weather monitors in their backyard. How do you get this real time data out to the public? How do you design a program to take advantage of this data?
- Monitoring data won't help much with a risk assessment or permit if you have to wait one year for the data. You could build a monitoring requirement into a permit, monitor for X years and show consistently below thresholds then remove the monitoring requirement.

- Real time monitoring changes the regulatory paradigm. People will want action levels if monitored data reaches a certain level. Need to come up with action levels for real time monitoring data.
- Fenceline monitoring can act as a control for public information. If you get a high level, source will want to fix something to reduce that level.

Many programs prioritize their permitted facilities in order to determine which facilities must go through all steps of a tiered process. The New York program assigns environmental ratings to individual air contaminants being emitted, after certain facility characteristics are first considered, such as proximity of facility to residences or other sensitive environmental receptors and existing ambient concentrations of the air toxics under review. SCAQMD prioritizes their permitted facilities and assigns them levels of either high-priority, interim-priority, or exempt; only the high-priority sites are required to perform a (human) health risk assessment. The Rhode Island program also prioritizes their permitted facilities based on emissions concentrations and other considerations, such as concerns about odors or health impacts; proximity of facility to other sources of air emissions, residential areas, schools, and other sensitive receptors; and consideration of elevated short-term emissions of an air toxic.

Program	Program Description
Louisville, Kentucky	Protection of both human health and the environment is encompassed in the Strategic Air Toxics Reduction program-related regulations. When the STAR program recommends application of best available technology for air toxics, which they refer to as T-BAT, it is stated that T-BAT must take into account "energy, environmental, and economic impacts and other costs, and health and welfare benefits." Their regulatory definition of welfare states "when referring to effects on welfare, includes, but is not limited to, effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants." Summation of cancer risks are addressed based on Environmental Acceptability Goal values of 7.5 in one million for cancer risks from all processes or process equipment from a single existing stationary source or 3.8 in one million for a new stationary source. Target-organ-specific Hazard Index analysis is required for any request to modify the Environmental Acceptability Goal for a noncarcinogen.
New Jersey	Generally, multiple source modeling is only done when determining compliance with a National Ambient Air Quality Standard (NAAQS).
New York	The computer program called AG-1 is used as primary tool to implement ambient impact analyses required for all new or modified sources of air contaminants, and includes assessment of cumulative source impacts (also referred to as multiple point source impacts) by separating sources properly,

Program	Program Description
	rather than adding maximum results from each source. 6 NYCRR (New York Codes Rules and Regulations) Part 212 also applies to existing sources upon issuance of a renewal for an existing permit or registration. Proximity of facility to residences or other sensitive environmental receptors, including consideration of area's anticipated growth and projected maximum cumulative impacts; and taking into account emissions from all sources at facility under review and the pre-existing ambient concentration of the air contaminant under review (background) will be considered in setting an environmental rating for the facility. Note that environmental ratings are assigned to individual air contaminants. Annual guideline concentrations, used as screening values, are protective of the environment and public health. Originally, background concentrations were assumed to be insignificant or zero for non-criteria pollutants, due to uncertainty associated with establishing credible, non-industrial background concentrations for non-criteria pollutants. However, as part of pending new rules, National Air Toxics Assessment will be used to identify background concentrations of non-criteria pollutants. Odor detection values can be used to evaluate acceptable short-term impacts in a qualitative way only (not a quantitative way, due to uncertainty associated with odor data collection).
Rhode Island	New sources applying for permits must perform a multiple pathway Human Health Risk Assessment utilizing CalEPA's Risk Assessment Standalone Tool. Residents, non-resident sensitive populations, and maximally impacted workplaces must be assessed. Existing sources are included per Air Pollution Control Regulation No. 9. Cumulative effects of emissions of two or more air toxics that affect same organ system (i.e., indicates non-cancer effects) may be unacceptable even if Ambient Air Levels for the individual substances are not exceeded. Total cancer risk related to facility emissions impact to Maximally Exposed Individual and other receptors cannot exceed 100 in one million (10^{-4} risk). During facility prioritization process, consideration of other factors may shift a source to a higher priority position. Such other factors can include: concerns about odors or health impacts; proximity to other sources of air emissions or to residential areas, schools, sensitive receptors; elevated short-term emissions of a substance with a 1-hour or 24-hour Ambient Air Levels.
South Coast Air Quality Management District (CA)	Considers cumulative risk from multiple chemicals coming from single source as part of Tier 1 screening emission levels. (Rule 1401 & 212 – new and modified sources). Multiple pathways adjustment factors are used during calculation of risks and hazards in the Tier 2 step (1401 & 212 – new and modified sources). No evidence that ecological risk or secondary effects are considered in the risk assessment process. It also does not appear that they consider airshed-wide

Program	Program Description
	risk, although in some cases background risks related to criteria pollutants are used in conjunction with facility risks to make decisions about respiratory health effects. Rule 1402 has goal of reducing health risks related to emissions of Toxic Air Contaminants from existing sources by specifying limits for maximum individual cancer risk, cancer burden, and noncancer acute and chronic (8-hr and chronic) Hazard Index applicable total facility emissions and requiring risk reduction plans to achieve specified risk limits. Health risk assessments required for any subject facility whose emissions exceeds a significant risk level (100 in one million or a Hazard Index of 5) or an action risk level (25 in one million, Hazard Index of 3).
Washington	Background concentrations of Toxic Air Pollutants will be considered as part of Second-Tier review (i.e., a Health Impact Assessment). WAC 173-460-090 states that the Health Impact Assessment will use existing data and characterize risks, including existing Toxic Air Pollutant sources in the area, and anticipated risk from new source. The rule specifies that background can be determined in one of three ways: 1) The latest National Air Toxics Assessment concentration at the appropriate census tract 2) Ambient monitoring data for the project's location (note: this is not practical or ever considered unless it was located near the only National Air Toxics Trends Station site in the state) 3) Modeling of emissions of the Toxic Air Pollutants subject to second tier review from all stationary sources with 1.5 kilometers of the source location. The rule does not specify how a consideration of the background concentrations may affect the final decision/acceptable risk. Health Impact Assessments must include additive cancer risk for all carcinogenic Toxic Air Pollutants which may be emitted by the source. Although not directly related to the assessment of cumulative risk, the first step involves comparing each Toxic Air Pollutant emission rate to its respective de minimis levels.

The following information was gathered at the July 27, 2016 Technical Workgroup meeting:

Pros and Cons of methods to set risk based concentrations:

- Flexibility is important in the sense that WA's list is written in rule. If they want to update list and add new pollutants or change a concentration, it would require rulemaking, a long process for a relatively small change. It's better to be able to make changes outside of rulemaking. Can the list of pollutants be separate from rule?
- If you want maximum flexibility but also want to go with primary sources as EPA or CalEPA, you need a flowchart for when they disagree, like whether something causes cancer or not. If you use a hierarchy, you still need to be able to decide when the RBCs don't agree.

- These are good things to consider when developing a list. Timeliness should be highlighted as an issue. Recent research is changing things. EPA's IRIS numbers are quite old and not valid. For example, cadmium has had many biomedical studies that have changed how we look at cadmium. Flexibility is critical at looking at what's going on currently. Consider European Union information because they look at more toxics than the US does.
- For the hierarchy used at EPA, the Science Advisory Committee said you need to be able to consider latest science. Keep the list as flexible as possible. EPA has RBCs for about 140 chemicals. To add to list is very difficult. If you add chemicals, how do you address existing sources?
- Values from different agencies vary. The website, ITIR, compares different databases and saves time. With the advancement in science, the values from EPA may remain the same, along with the uncertainty factors but the scientific methods may have changed. Make sure you use the advanced method to derive the current value.
- South Coast defers to CalEPA for toxicity data. If there is a process for determining RBCs, there is some thought given to input, public participation, and technical discussion because this is as technical as it gets. It can be very opaque to the public and stakeholders. Make sure the process for public and stakeholder input is clear and transparent.
- Look at a hybrid approach because not all pollutants will not fit into these boxes for setting RBCs. Some HAPs are in groups, not discrete chemicals. Do you treat all those compounds exactly the same? Bring in old and new databases to bring in good science.
- If you start with 187 HAPs, that may cover 90% of chemicals but you need to do something different for other 10%. That is a hybrid approach. Don't be tied to one method and lose sight of other methods that can be used.
- This is a great step by step approach to take. Don't limit yourself to peer reviewed literature. Most toxics literature is done by industry and trade groups but make sure it is done by reputable researchers with good laboratory practices. Industrial chemical studies have not been published. If it's not publicly available, then hard to provide to the public.
- The surrogate analysis, in relation to QSAR, is a single model. The read across approach is done manually and was sent to David.
- Consider GLB studies too. NIOSH gets papers in different languages and pays for translation and use.

Pros and Cons of using default toxicity values

- You can't be too conservative or not conservative enough. The New York approach having low, medium and high toxicity bins is good.
- Default toxicity values should be used as a last resort. Other better approaches you could use are route to route extrapolation and QSAR (preferable).
- Look at similarities to other compounds that are better known. Being able to look at similarities and differences helps you look at other chemicals. Having default value as a last resort can be very helpful.
- If a facility is going to emit an unknown chemical, put burden back on industry to prove risk from that chemical. Industry should have some idea of where it fits on a hierarchy instead of using default toxicity values.

- SCAQMD doesn't use default toxicity value. Apply some caution with this approach because you need a trigger to say is something toxic. Do we have reason to believe that it is toxic? You need other steps before you trigger the default value. This is the precautionary principle in action, using default toxicity values.
- NIOSH uses a hazard banding approach, like a GHS classification of a chemical. This is a higher level approach than a default toxicity value. There is a framework for using hazard banding. When you have chemical x, if you don't have risk values or do a surrogate analysis as a precautionary approach, you go to the framework and check the information you have for that chemical. Based on that information, the chemical is banded as high, medium, or low toxicity.

Pros and Cons of modifying occupational or chronic RBCs to generate acute RBCs

- This falls to the method of last resort when there are no other options. TLV evolvement differs dramatically in that they are based on a NOEL or LOEL approach. Others are based on what caused an irritant in an occupational population. Some RBCs are risk based, some are irritant basis. Dividing TLV by 100 doesn't make toxicological sense. You need the foundational information on what that TLV is based on.
- Going from chronic to acute RBCs doesn't make sense because acute toxicity looks at the irritant property and short term health effects. Chronic studies find maximum tolerated doses and often times they did short term studies so literature could be available. You need the acute study on which chronic study was based.
- Information for going from subchronic to chronic has you divide by 10. Multiplying by 10 wouldn't be enough. Studies have been done that show if you don't have a chronic study for a chemical and only have subchronic information, then what can we do? In 1980s and 90s, but still that was set a long time ago.
- When WA was trying to figure out what to do about acute affects, there were a couple schools of thought. Try to use Haber's Rule which is a function of the concentration and time you are exposed, and depends on how much concentration and long exposed, exponential decline in time. You don't know the constant for most chemicals you are dealing with. An alternate approach is if you are looking at annual concentration and extrapolate to short term, 8760 hours/year, which is not scientifically defensible. If something is published, use it. Don't use chronic toxicity as a screening concentration.

Statewide air toxics overview

- All monitoring for metals was shown as PM10. TSP might be worth considering rather than just PM10. The different targets for Portland and La Grande are aspirational targets to make continued progress. This slide is helpful but can be something to think about for risk communication. You need to state the ultimate risk reduction goal for 2020 or other out year.

Setting and administering acceptable risk levels is critical to protecting public health. The following are policy questions that should be addressed to ensure the program is protective of public health.

Do DEQ and OHA have the technical information assembled in this issue paper to inform these policy choices? Are there unique aspects of air toxics permitting programs not described in this paper that DEQ and OHA should consider? Is there technical information or considerations missing from this issue paper?

- How should DEQ/OHA define the acceptable risk level? What will be protective of public health?
- Should there be different risk levels for new, modified or existing sources?
- What actions should be taken if risk levels are not met?
- Should there be a different risk level allowed if a facility has T-BACT in place?
- Should DEQ/OHA require or allow the assessment of multiple pathways risks?
- Should cumulative health risks be addressed, and if so, when? How should cumulative risk be addressed?
- Should Oregon's program address environmental effects and welfare issues as well as human health?
- Should Oregon's program account for pollutants from other sources, including background? If so, how?
- How conservative should DEQ's program be? In the end, how does DEQ ensure that the choices made are sufficiently conservative? Toxicity? Acceptable ambient levels? Thresholds for applicability?