Overview of Hazard Index Rulemaking

State of Oregon Department of Environmental Quality

Background

Cleaner Air Oregon (CAO) is Oregon's program to prevent harm to the health of people who live, work, or learn near industrial facilities that emit toxic air contaminants. The Department of Environmental Quality (DEQ), with support from the Oregon Health Authority (OHA), developed the program at the direction of Governor Kate Brown starting in April 2016. CAO requires industrial facilities to report their emissions of toxic air contaminants, to assess the risk to public health to neighbors from those emissions, and to reduce emissions if levels are above requirements adopted in CAO rules.

The Environmental Quality Commission (EQC), the policy body that oversees DEQ, adopted the rules for the majority of CAO in November 2018 with input from a Rules Advisory Committee that met between October 2016 and August 2018. During this period, in March 2018, the Oregon legislature enacted Senate Bill (SB) 1541 directing DEQ modify certain aspects of the program. One of these was the level of risk at which facilities are required to reduce emissions for chemicals that are known to have developmental, reproductive, respiratory, or other noncancer health effects. SB 1541 allows, for a period of 10 years, a higher level of risk from facility emissions for noncancer risks. The legislation also allows the EQC, after convening and receiving information from a Technical Advisory Committee, to set lower allowable risk levels for certain chemicals expected to have developmental or other severe human health effects. DEQ is now conducting a separate rulemaking to set these alternative risk levels, known as hazard index (HI) levels, and is reconvening the CAO Rules Advisory Committee to inform development of proposed rules.

Rulemaking Purpose

The role of CAO Rules Advisory Committee is to advise DEQ and OHA on the proposed approach for writing rules for Section 7 of SB 1541. These rules identify which toxic air contaminants will be regulated at an HI other than 5, and detail other changes necessary for implementation. The criteria for any proposed revisions to established HI benchmarks are outlined in SB 1541 and the proposed rule approaches in this document have been informed by the discussions of a Technical Advisory Committee appointed by the EQC and convened by DEQ in fall 2018. DEQ is conducting the HI rulemaking process separately from the main CAO rulemaking process, which concluded in November 2018, to allow implementation of the core program to get underway.

Additional Information

Senate Bill 1541

SB 1541 established several parameters and requirements for any future rules adopted as part of the Cleaner Air Oregon program, including certain benchmarks for existing (permitted) facilities. Specifically, the legislation set the noncancer benchmark, or risk action level, at an HI of 5. The proposed rules at that time had a benchmark of an HI of 1.

In addition, Section 7 of SB 1541 states that the EQC can assign an HI other than 5 (but not lower than 3) as the Risk Action Level applicable to existing facilities for toxic air contaminants identified as having "developmental human health effects associated with prenatal or postnatal exposure" or "other severe human health effects." See SB 1541 in its entirety here.

Hazard Index

Noncancer health risk from air contaminants is measured using an HI. An HI is calculated by comparing the amount of each chemical present in the air with the amount of each chemical that is not expected to harm health. HIs are explained in more detail here. An HI below 1 means a person breathing a facility's emissions is not expected to experience health effects. An HI greater than 1 means a person breathing a facility's emission may experience health effects. The higher the HI number, the higher the potential risk to health. For example, an HI of 3 means that exposure to a facility's emissions is three times the level that is not expected to harm health.

A facility regulated under CAO must evaluate its toxic air contaminant emissions against a risk action level (RAL). A RAL is the level above which facilities must take action related to their air toxics emissions in CAO. Some of the RALs in CAO rules are called benchmarks in SB 1541. The current proposed CAO rules set a noncancer benchmark HI value of 5 as the RAL at which existing permitted facilities are required to evaluate reducing risks from emissions (Figure 1). RALs are described in more detail here. The RAL of an HI value of 5 is established by law in SB 1541. Note that SB 1541 established a benchmark for new permitted facilities at 1 (consistent with proposed rules at that time). Figure 2 illustrates the different RALs an existing facility must address depending on the HI of facility emissions, as identified by the risk assessment process.

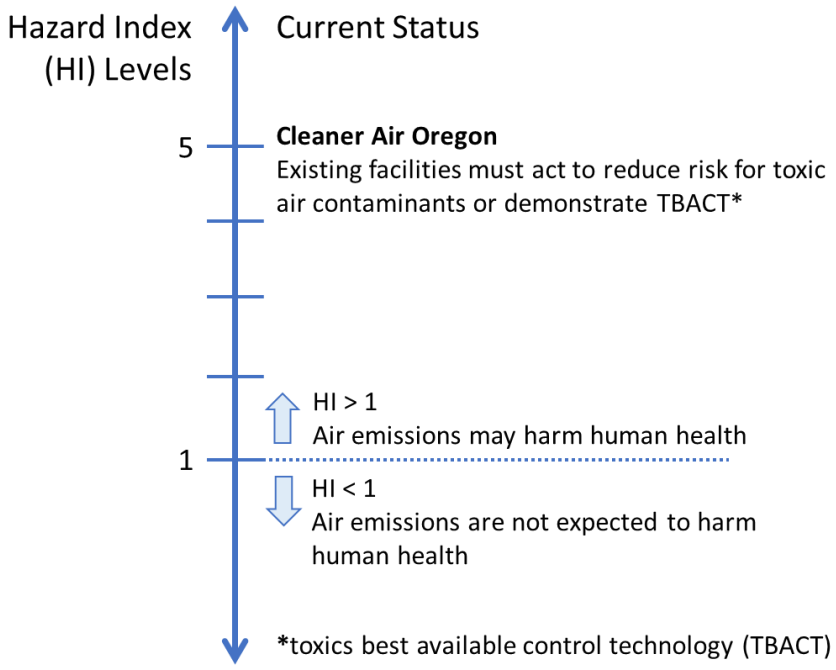

Figure 1. The HI level at which air emissions may harm human health (HI >1) relative to where the current proposed CAO rules set the noncancer benchmark HI value (HI > 5).

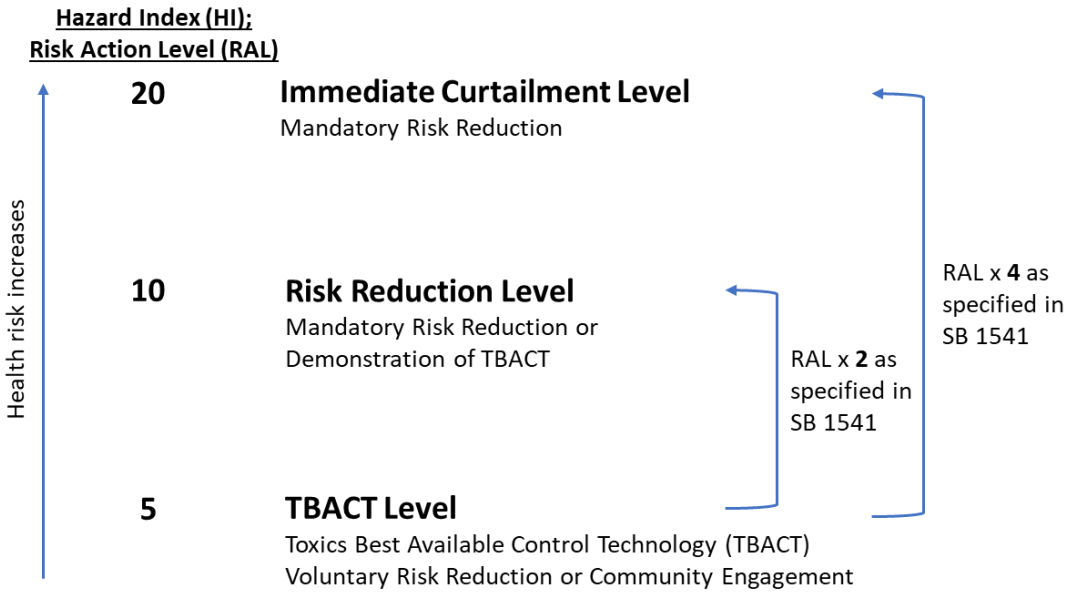

Figure 2. RALs for noncancer risk from existing facilities.

Technical Advisory Committee

SB 1541 directed the EQC to convene and consult with a Technical Advisory Committee with expertise in toxic air contaminant risk assessment to determine which toxic air contaminants are associated with developmental or other severe human health effects. In 2018, DEQ worked with OHA to identify appropriate candidates to serve on the HI Technical Advisory Committee. The details of this process are available on the HI website, accessible here.

The HI Technical Advisory Committee met for all-day public meetings on October 23, 2018 and December 4, 2018. DEQ and OHA staff provided the HI Technical Advisory Committee with relevant technical information prior to, during, and after these meetings, but did not direct the HI Technical Advisory Committee as to how to make committee decisions. Committee members were asked to provide input; DEQ did not require committee members to come to consensus or develop findings. DEQ documented all input from the HI Technical Advisory Committee in meeting minutes and audio-recorded the meetings. DEQ and OHA considered HI Technical Advisory Committee input in preparing the information presented to the Rules Advisory Committee. Detailed minutes from the HI Technical Advisory Committee Meetings are available here.

Outcomes from Technical Advisory Committee and Potential Changes to RALs

During the Technical Advisory Committee meetings, committee members and DEQ/OHA staff discussed and concluded that there is not a clear science-based way to distinguish the noncancer adverse health risk that should or should not be considered "severe." This is because the science classifies health risks according to the organ or system affected (e.g., reproductive, cardiovascular, respiratory). Other key points of discussion included scope of developmental effects, toxicity from acute versus chronic exposures, consideration of authoritative sources other than those currently in CAO rules, ethics, and protocols to update the target organ spreadsheet (TOS; see discussion below). After significant discussion, a majority of the HI Technical Advisory Committee members concluded that:

- Reproductive effects should be considered a developmental effect. Therefore, developmental effects and reproductive effects should be evaluated as one combined category of effect, and not assessed separately.
- Hazard identification rather than dose response is the appropriate metric for classifying a toxic air contaminant expected to have developmental health effects. In other words, a majority of committee members advised that if there is evidence that the contaminant causes developmental or reproductive health effects at any dose, then it should be designated as a developmental or reproductive contaminant.
- There is no available science-based process to determine which chemicals are and are not expected to have "other severe human health effects." All human health effects can be considered severe, depending on the person experiencing them. Adverse health effects from chemical exposure can also affect sensitive individuals to a higher degree relative to other individuals due to a wide variety of factors. As an analogy, a bee sting will cause a potentially life-threatening allergic reaction in some individuals but cause relatively little harm to health in other individuals.
- Given the limited language of the statute regarding the definition of "severe", the Technical Advisory Committee had several potential suggestions as to how it could be defined but ultimately had no majority recommendations.

The points above reflect broad agreement among a majority of committee members. Individual committee members introduced other topics described in the full meeting minutes available here.

Resources Developed - Target Organ Spreadsheet

To help clarify which toxic air contaminants are expected to have developmental, reproductive, or other health effects, OHA and DEQ developed a spreadsheet (called the Target Organ Spreadsheet, or TOS). The TOS describes which organs or organ systems are potentially affected by each toxic air contaminant. The HI Technical Advisory Committee was appreciative of this spreadsheet and provided additional feedback on how to improve and use the TOS. The TOS is available here.

To develop the TOS, DEQ and OHA toxicologists drew from the widely-recognized authoritative sources cited in the CAO rules. The list of authoritative sources is described in OAR 340-245-0300 and presented below.

- DEQ Ambient Benchmark Concentrations specified in OAR chapter 340 division 246;
- DEQ and OHA Short-Term Guideline Concentrations;
- U.S. EPA Integrated Risk Information System (IRIS) or Office of Superfund Remediation and Technology Innovation (OSRTI);
- United States Agency for Toxic Substances and Disease Registry (ATSDR); and
- California's Office of Environmental Health Hazard Assessment (OEHHA).

These authoritative sources use a robust, transparent, and peer-reviewed process to evaluate, synthesize and summarize information about the health effects and toxicity of toxic air contaminants after reviewing available research studies and making conclusions based on the weight of scientific evidence. Therefore, publication of target organ information by one of the authoritative sources listed above and in OAR 340-245-0300 will serve as

the criteria that DEQ will use to determine how to adjust benchmarks for noncancer risk as directed by SB 1541, Section 7(2).

DEQ and OHA staff wrote and followed a set of inclusion criteria, which were reviewed by and refined with input from the HI Technical Advisory Committee, to ensure that information was added to the TOS and reviewed in a consistent way. DEQ and OHA staff documented these criteria here. Three agency toxicologists reviewed and verified each TOS entry in a manner consistent with the inclusion criteria.

Options for Adjusting HI-based RALs

There are a range of potential options for adjusting HI-based RALs in response to SB 1541. In consideration of input and recommendations received during the Technical Advisory Committee meetings, DEQ and OHA developed two options for adjusting the benchmarks for excess noncancer risk. Each option includes a description, an illustrative figure, and a brief discussion of the feasibility and implications of the option.

Option 1

Description

All 184 toxic air contaminants that have noncancer toxicity reference values would be regulated at a RAL of an HI of 3 (Figure 3). Currently, all these contaminants are regulated at a RAL of an HI of 5. All of these chemicals have an effect on one or more target organs/systems, which include kidney, liver, blood, endocrine system, musculoskeletal system, eyes, skin, central nervous system, peripheral nervous system, cardiovascular system, immune system, respiratory system, reproductive system, gastrointestinal system, and developmental effects. All of these effects can be considered to be potentially severe human health effects.

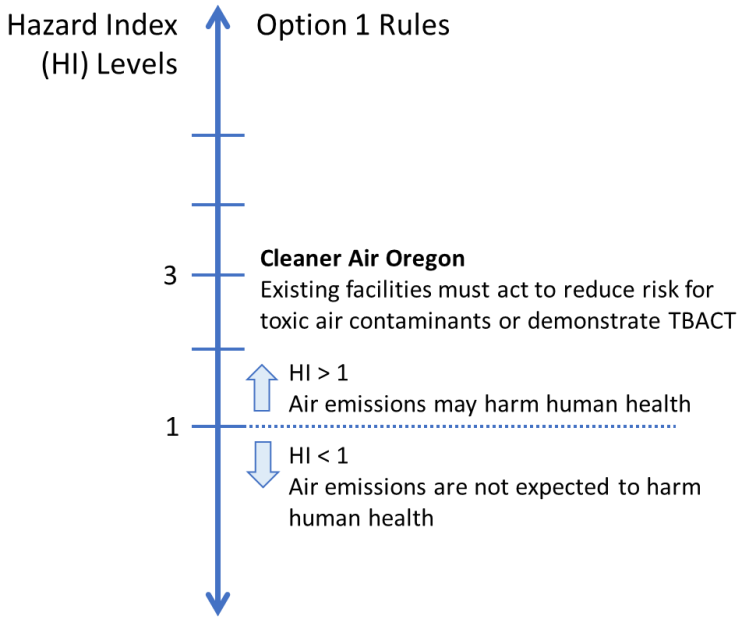

Figure 3. One option for adjusting HI-based RALs in response to SB 1541; existing facilities must act to reduce risk for all toxic air contaminants or demonstrate TBACT when the HI is greater than 3.

Feasibility

With all 184 contaminants with noncancer health effects regulated at the same RAL of an HI of 3, the HI calculations remain a straightforward process. This follows the same procedures as already described in the main CAO rules (adopted in November 2018).

Implications

- Most health-protective option; considers an individual's specific sensitivities to toxic air contaminants
- Simpler risk calculations compared to option 2
- Some existing facilities may be required to take action that otherwise would not be required (e.g. HI 4 or 5)

Option 2

Description

Of the 184 toxic air contaminants with noncancer health effects, DEQ and OHA identified 141 (77%) compounds expected to have developmental or reproductive human health effects associated with prenatal or postnatal exposure, which would be regulated based on a RAL of an HI of 3 (Figure 4). Chemicals expected to have developmental or reproductive human health effects are clearly identified in the TOS resource. In the absence of a science-based definition for the word "severe," the remaining 43 (23%) toxic air contaminants with noncancer risk would remain regulated based on a RAL of an HI of 5 (Figure 4). Additional background information on which toxic air contaminants are and which are not expected to cause developmental or reproductive health effects are provided here.

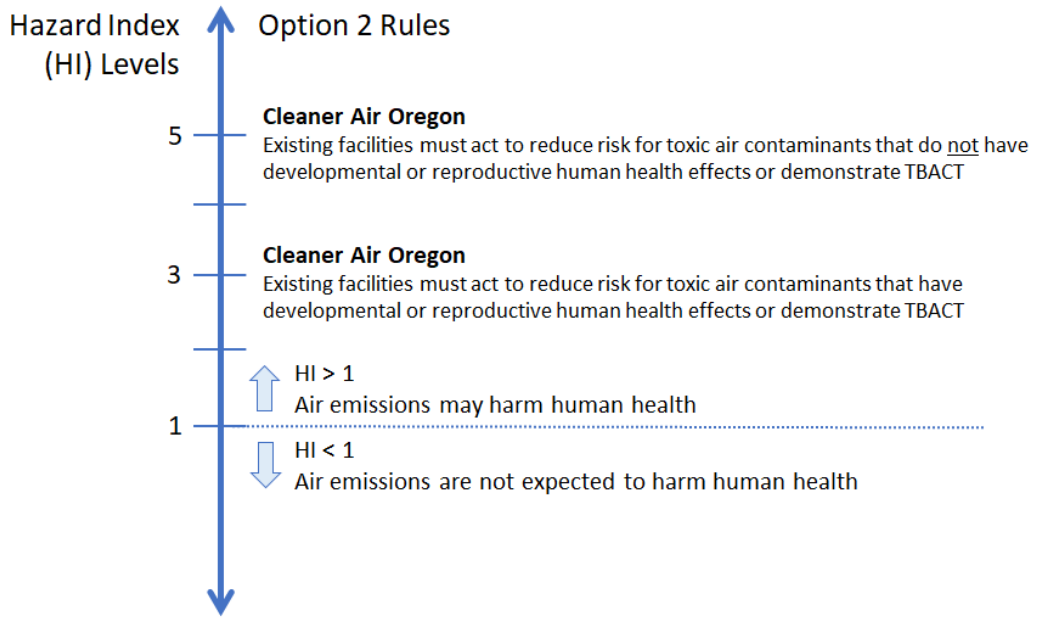

Figure 4. Another option for adjusting HI-based RALs in response to SB 1541; certain toxic air contaminants (with developmental or reproductive health effects) would be regulated at an HI of 3 and others toxic air contaminants (that do not have developmental or reproductive health effects but have other types of human health effects) would be regulated at an HI of 5.

Feasibility

A challenge with Option 2 is when a facility emits a mix of toxic air contaminants that are regulated at both an HI of 3 and an HI of 5. In this circumstance, DEQ would propose requiring the source to perform an analysis of risk that considers both benchmarks simultaneously. The process would involve calculation of a ratio, called an "exceedance ratio," which weights the noncancer risk from a source's emissions relative to both HI benchmarks of 3 and 5. To sum noncancer risk related to a mixture of HI3 and HI5 chemicals, the formula below would be used to obtain exceedance ratio values (Formula 1). The exceedance ratio would be calculated separately for chronic noncancer risk and for acute noncancer risk. If a particular exceedance ratio is exceeded, then so would the related RAL.

Formula 1. How to calculate an exceedance ratio.

$$Risk_{HI3} = \sum_{HI3\ chemicals} \frac{Concentration}{Risk\ Based\ Concentration}$$

$$Risk_{HI5} = \sum_{HI5\ chemicals} \frac{Concentration}{Risk\ Based\ Concentration}$$

$$Exceedance\ Ratio = \frac{Risk_{HI3}}{3} + \frac{Risk_{HI5}}{5}$$

HI3 = Toxic air contaminants assigned noncancer TBACT RAL of 3.
HI5 = Toxic air contaminants assigned noncancer TBACT RAL of 5.

- An exceedance ratio greater than 1 means the facility's risk is above the TBACT RAL. DEQ would require the facility to either reduce risk or demonstrate that they have the best controls in place (TBACT).
- An exceedance ratio greater than 2 means the facility's risk is above the risk reduction RAL. DEQ would require the facility to reduce risk even if it already has the best controls in place (TBACT).
- An exceedance ratio greater than 4 means the facility's risk is above the immediate curtailment RAL. DEQ would require the facility to immediately act to reduce risk.

Implications

- Less health-protective than option 1
- Requires complex risk calculations
- Fewer facilities would have to make investments in emissions reductions