State of Oregon Department of Environmental Quality

Overview of Proposed Hazard Index Rules

October 2019

Background on CAO Rulemaking

Cleaner Air Oregon 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, with support from the Oregon Health Authority, 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 potential health risks to neighbors from those emissions, and to reduce emissions if levels are above CAO requirements.

The Environmental Quality Commission, the policy body that oversees DEQ, adopted the rules for CAO in November 2018 with input from a Rules Advisory Committee that met between October 2016 and August 2018. In March 2018, the Oregon legislature enacted Senate Bill 1541, which authorized and funded the CAO program and set parameters and requirements for future program rules. CAO rules establish benchmarks, or Risk Action Levels, at which permitted facilities must either reduce emissions or demonstrate that the best available controls are in place. Benchmarks that correspond to a noncancer health risk are expressed in terms of a Hazard Index number.

SB 1541 set noncancer benchmarks for existing facilities at an HI of 5. It also established a process that allows DEQ to identify certain chemicals expected to have developmental, reproductive, respiratory, or other noncancer health effects. For these chemicals, SB 1541 allowed DEQ to set benchmarks for noncancer RALs lower than an HI of 5, but no lower than an HI of 3, for existing facilities. This mean that DEQ is setting stricter requirements on chemicals that have developmental and other severe health effects. See SB 1541 here. Before adjusting benchmarks, however, SB 1541 required the EQC to consult with a technical advisory committee. The Technical Advisory Committee convened on October 23 and December 4, 2018.

Hazard Index Rulemaking

DEQ undertook the HI rulemaking separately from the main CAO rulemaking process, which concluded in November 2018, to allow implementation of the core program to get underway. DEQ reconvened members of the original CAO Rules Advisory Committee (July 10, 2019) to serve as the HI rulemaking Rules Advisory Committee.

The Technical Advisory Committee, Rules Advisory Committee, and Fiscal Advisory Committee each gave science- and policy-based recommendations for DEQ to consider. DEQ's proposed HI rules identify which noncancer toxic air contaminants will be regulated at an HI other than 5 in the CAO program, and include other changes necessary for DEQ to effectively implement the rules.

Hazard Index and Risk Action Levels

Here, an HI is calculated by comparing the amount of each chemical present in emissions with the amount of that 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 noncancer health effects. An HI greater than 1 means a person breathing a facility's emission may experience noncancer 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 RAL. The current CAO rules, as required by SB 1541, set a RAL for existing permitted facilities; facilities must either demonstrate that they are using the best available control technology or reduce risk below a noncancer benchmark of HI 5 (Figure 1). RALs are described in more detail here. 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.

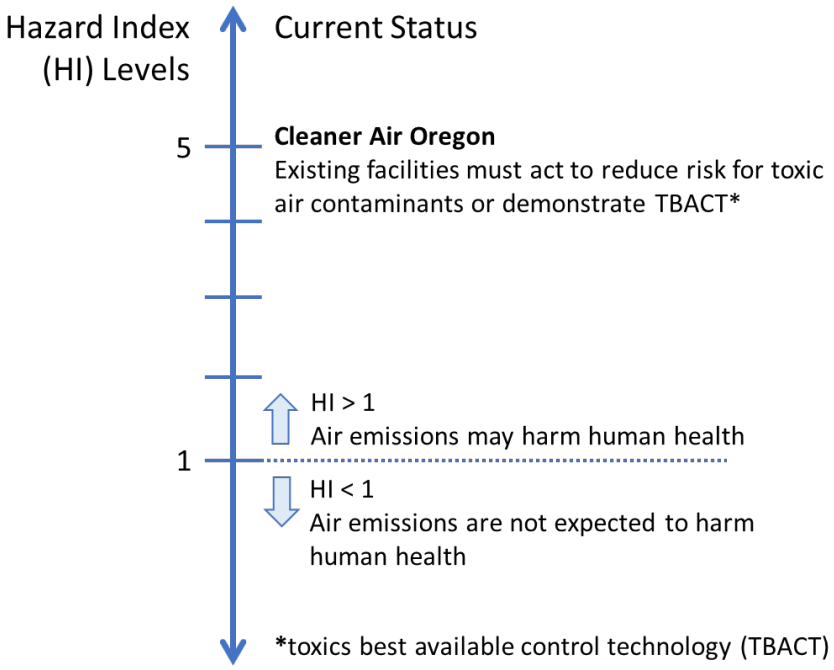

Figure 1. The HI level at which air emissions may harm human health (HI >1) relative to where the current proposed CAO rules set the noncancer benchmark HI value (HI > 5).

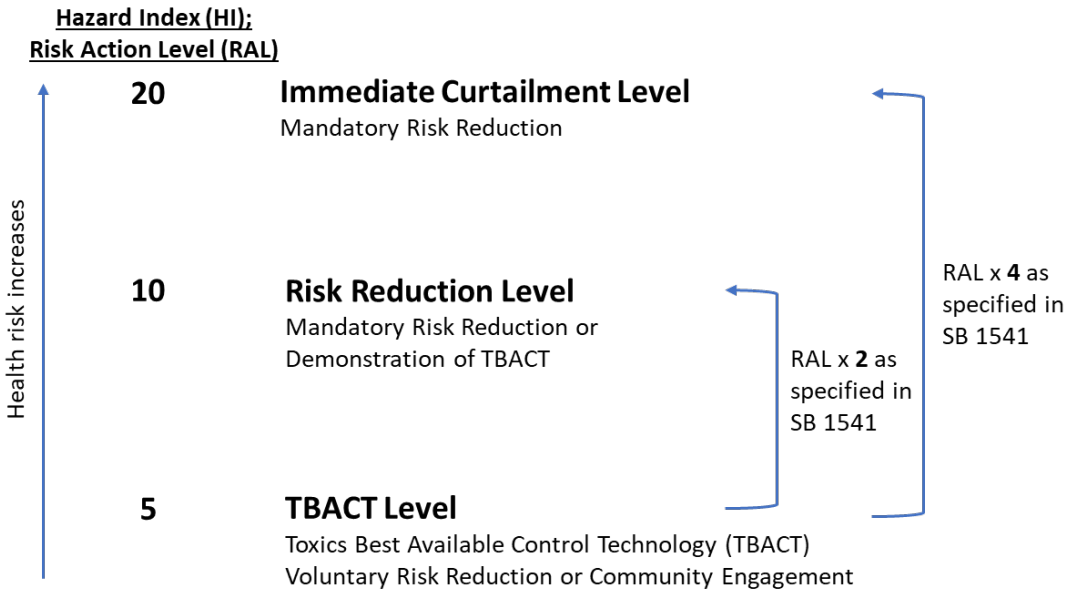

Figure 2. RALs for noncancer risk from existing facilities.

Technical Advisory Committee

SB 1541 directed the EQC to convene and consult with a Technical Advisory Committee having 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 Cleaner Air Oregon Hazard Index Technical Advisory Committee 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's decision - making process. Committee members were asked to provide input; DEQ did not require committee members to come to consensus on recommendations. DEQ documented all input from the HI Technical Advisory Committee in meeting minutes and audio-recorded the meetings. Detailed minutes from the HI Technical Advisory Committee meetings and additional comments submitted after the meetings by some TAC members are available here.

Outcomes from Technical Advisory Committee

During the Technical Advisory Committee meetings, committee members and DEQ/OHA staff discussed how to distinguish "severe" noncancer adverse health risk. The TAC concluded that there is not a clear science-based way to do this since 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. 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.

The points above reflect broad agreement among a majority of Technical Advisory Committee members. Individual committee members introduced other topics described in the full meeting minutes, and comments were submitted by some TAC members after the meetings.

Hazard Index 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. The TOS describes which organs or organ systems are potentially affected by each toxic air contaminant. The HI Technical Advisory Committee 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 or Office of Superfund Remediation and Technology Innovation;
- United States Agency for Toxic Substances and Disease Registry; and
- California's Office of Environmental Health Hazard Assessment.

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. DEQ considered publication of target organ information provided by one of the authoritative sources listed above and in OAR 340-245-0300 as a standard for determining the degree of adjustment to noncancer benchmarks, as directed by SB 1541, Section 7(3)(B).

DEQ and OHA staff wrote and followed a set of inclusion criteria, which were reviewed by and refined with input from the HI TAC, 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.

Outcomes from Rules Advisory Committee: Options for Adjusting Hazard Index-based RALs

After receiving input and recommendations from the Technical Advisory Committee, DEQ and OHA developed two discussion rule options for adjusting the benchmarks for excess noncancer risk and presented those to the

Rules Advisory Committee. The RAC considered the two proposed rule options and provided input and suggestions to DEQ and OHA. The details of the RAC discussions, as well as materials presented to the RAC, can be found here.

DEQ and OHA also presented a methodology that allows calculation of a facility-specific HI value for a mix of HI 3 and HI 5 toxic air contaminants emitted by an existing facility. This methodology involves use of a ratio, called a "Risk Determination 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 HI 3 and HI 5 chemicals, the formula below would be used to obtain Risk Determination Ratio values (Formula 1). The Risk Determination Ratio would be calculated separately for chronic noncancer risk and for acute noncancer risk. If a particular Risk Determination Ratio is exceeded, that would trigger the related RAL.

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

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

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

Formula 1. How to calculate a Risk Determination Ratio. HI 3 = Toxic air contaminants assigned noncancer TBACT RAL of 3. HI 5 = Toxic air contaminants assigned noncancer TBACT RAL of 5.

- A Risk Determination 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.
- A Risk Determination 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.
- A Risk Determination 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.

Suggestions from the RAC

A suggestion from members of the RAC for the definition of "severe" noncancer human health effects, included considering toxic air contaminants with Toxic Reference Values that are based on more than one target organ effect as severe. DEQ and OHA staff agreed with this suggestion. Additionally, a RAC member expressed concern about phosgene, which is a chemical known to be very hazardous to human health, potentially being regulated at an HI of 5 under one of the options presented by DEQ. In response, DEQ and OHA considered information from the U.S. Department of Transportation, which lists chemicals that are inhalation hazards under Hazard Classes 2.3 and 6.1. These chemicals are "known to be so toxic to humans as to pose a hazard to health during transportation" (49 CFR 173.115). The chemicals pose inhalation hazards during transportation via volatilization, aerosolization, or particulate dispersion. There are 13 chemicals that are classified by DOT as inhalation hazards and also are listed in the CAO rules as having noncancer health effects. All but two of those chemicals were already on the list of chemicals proposed for regulation at an HI of 3.

Proposed Rule Description

Based on the requirements in Section 7 of SB 1541, DEQ is proposing rules based on regulation of noncancer risk for existing facilities. The two main rule changes to the overall CAO program that would occur as a result of adoption of these proposed HI rules are:

1) 156 toxic air contaminants would be regulated at a noncancer RAL of an HI benchmark of 3, while the remaining 26 toxic air contaminants would be regulated at a RAL with an HI benchmark of 5. Toxic air contaminants proposed to be regulated at an HI of 3 have been identified as either having developmental or other severe human health effects.
2) A new methodology would be used that allows calculation of a facility-specific HI value for a mix of HI 3 and HI 5 toxic air contaminants emissions, called the Risk Determination Ratio.

Integrating both science- and policy-based feedback from the Technical and Rules Advisory Committees, DEQ and OHA used multiple lines of evidence to designate chemicals expected to have severe health effects (Table 1).

Table 1. Criteria for regulation at an HI benchmark of 3.

		Number of Toxic Air Contaminants
Developmental Health Effects		132
Other Severe Health Effects	Reproductive Health Effects	116
	Multiple Target Organs	63
	U.S. Department of Transportation Inhalation Hazards	13
Expected to have Developmental and/or Other Severe Health Effects		**156**

The numbers of toxic air contaminants identified in each Table 1 category do not add up to 156 because 114 of these chemicals (75%) appear in more than one category (Figure 3). Facilities that emit a mix of toxic air contaminants regulated at both an HI of 3 and an HI of 5 would establish a RAL by calculating the risk determination ratio described in the preceding section.

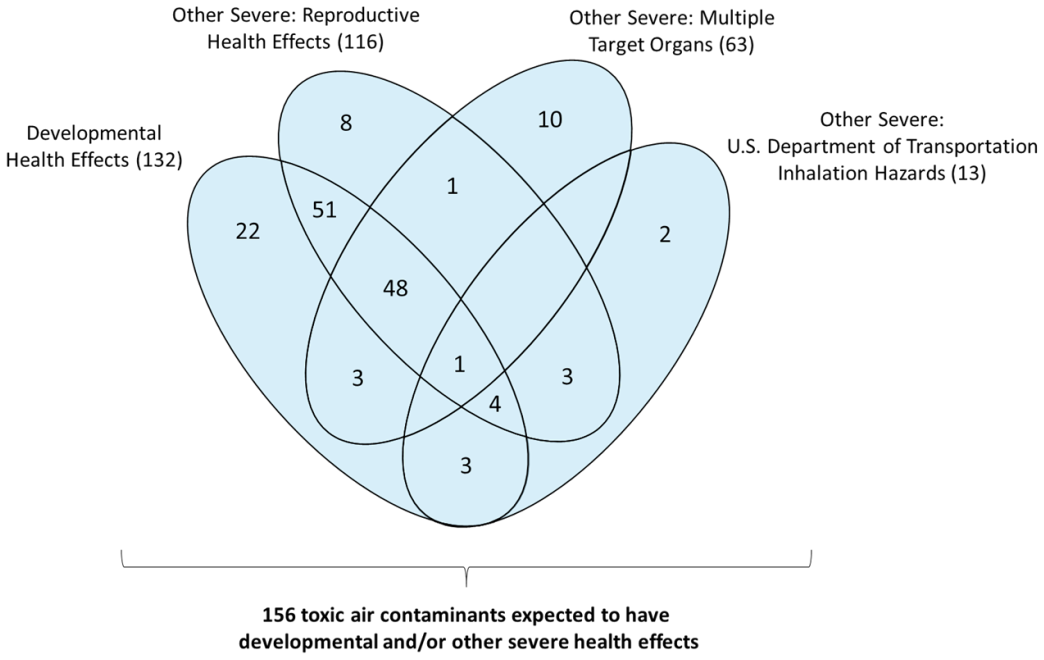

Figure 3. Venn Diagram of the toxic air contaminants that overlap between different categories of chemicals that are expected to have severe human health effects.

Outcomes from Fiscal Advisory Committee

The DEQ convened a meeting of the Hazard Index Fiscal Advisory Committee, or FAC, as required by statute, on Sept. 23, 2019. The FAC is required to consider the potential fiscal impacts of the proposed Hazard Index rules; whether there is a significant fiscal impact to small businesses; and, if there is, provide suggestions on how that impact to small businesses might be mitigated. The FAC as a whole thought that the proposed HI rules would cause fiscal impacts, but were divided on the question of whether or not small businesses would be significantly impacted, and also gave recommendation on possible mitigation strategies for small businesses. A more detailed account of the FAC discussions can be found here.