STATE OF NEW HAMPSHIRE

Department of Environmental Services
Environmental Health Program
Inter-Department Communication

To:	Karla McManus, MS, JD, Rules Manager Todd Moore, Air Permits Program Manager	**Date:**	December 10, 2020
From:	David Larson, MPH, Health Risk Assessor	**Ec:**	Gary Milbury, PEHB Administrator Craig Wright, ARD Director
RE:	Formaldehyde (CASRN 50-00-0) AALs		

Pursuant to RSA 125-I:4, the New Hampshire Department of Environmental Services Air Resources Division (ARD) proposes changes to the list of regulated toxic air pollutants (RTAPs) and their ambient air limits (AALs) in Env-A 1400, *Regulated Toxic Air Pollutants.* These changes are based on updates made by the American Conference of Governmental Industrial Hygienists (ACGIH) and the USEPA's Integrated Risk Information System (IRIS) to the list of chemical substances. The ambient air limits established under this rule are intended "to promote public health by reducing human exposure to toxic chemicals by regulating releases of toxic chemicals into the ambient air" (NH RSA 125-I:1, Purpose).

Background

Env-A 1400 specifies a long-term (annual) and a short-term (24-hour) AAL be developed for each RTAP relying "on threshold limit values, reference concentration limits, and such other generally accepted scientific data as may be available" (NH RSA 125-I:4, Regulated Toxic Air Pollutants). The default methodology used by the Environmental Health Program (EHP) to calculate the annual and 24-hour AALs and *de minimis* emission levels can be found in sections Env-A 1409 and Env-A 1410 of the rule. These calculations typically rely on the use of the ACGIH threshold limit values (TLV) and/or an IRIS reference concentration (RfC).

At a stakeholder meeting held on September 8, 2020, ARD presented the revised draft AALs, including those for formaldehyde. Several stakeholders noted that the proposed formaldehyde AALs were such that, regardless of how low their emissions were, that the proposed AALs would be nearly impossible to achieve in practice. They subsequently followed up with information which supported an approach that would result in less stringent AALs, noting that RSA 125-I:4 provides for the use of other methods to calculate AALs where appropriate.

The EHP reviewed the submitted information and conducted additional research to determine if revising the draft formaldehyde AALs is warranted. The EHP notes that the conservative risk-based approach for calculating an ambient air concentration typically assumes an exposure of 24-hours per day, 365 days per year for an assumed lifetime of 70 years. Using these assumptions, the risk based concentration (0.078 $\mu g/m^3$) is less than background in NH (0.92 $\mu g/m^3$) according to the NATA assessment of 2014. The EHP reviewed the formaldehyde USEPA IRIS assessment and notes it was last updated in 1990 and the IRIS inhalation Unit Risk (URi) factor extrapolation method is the linear multistep procedure. Since the 1990 IRIS posting, USEPA began reassessing formaldehyde in 1998 and released a draft IRIS reassessment in June 2010 based on additional research that had been conducted since the original assessment. Scientists are currently debating the

carcinogenic properties of formaldehyde and the ways that it may cause cancer. Given the complexity of the issues, the USEPA asked the National Research Council (NRC) to conduct an independent scientific review of the draft IRIS assessment. NRC completed the review and provided comments to the USEPA in 2011 (NRC, 2011). Currently, the IRIS web page identifies the formaldehyde draft reassessment as officially suspended as of December 2018 (USEPA, 2020 Dec).

The literature search conducted by the EHP also identified several States as having conducted analyses of formaldehyde studies and determined that the mechanism of action for formaldehyde is non-linear, or based on a threshold. In August 2019, the Minnesota Department of Health (MDH) established a chronic scenario (>8 years – lifetime) health based value (HBV) ambient air concentration of 9 µg/m^3. MDH concluded:

> "Based on the current weight of evidence MDH will proceed with a non-linear mechanism of action for formaldehyde carcinogenesis. MDH noncancer subchronic and chronic HBVs (9 µg/m^3 each) is based on nasal irritation in humans, which is more sensitive than the cancer precursor effects of cytotoxicity and regenerative cellular proliferation. Therefore, the noncancer subchronic and chronic HBV is protective of cancer effects" (MDH, 2019).

Also, in 2008 the Texas Commission on Environmental Quality (TCEQ) conducted an analysis of formaldehyde studies and also concluded that the formaldehyde mechanism of action is non-linear (threshold) and established Reference Values (ReV) for non-carcinogenic (11 µg/m^3) and carcinogenic (18 µg/m^3) endpoints. In summary, the non-carcinogenic based ReV should be protective of the carcinogenic endpoint (TCEQ, 2008).

The EHP acknowledges that the primary source of toxicity values is the USEPA's IRIS database, and when risk based concentrations are being developed the EHP relies on IRIS toxicity factors. However, the formaldehyde URi is from 1989 and more recent analysis of formaldehyde studies by several States have concluded that the mechanism of action is non-linear (threshold) versus the linear approach USEPA used. For these reasons, the EHP proposes an approach for deriving the formaldehyde annual AAL that uses the USEPA's URi, but also recognizes the current state of the science. While the EHP recognizes that the revised approach will results in less conservative AALs than the default methodology and the conservative (70 years) risk based approach; the annual AAL is still well within the acceptable risk level as defined by the U.S. Environmental Protection Agency (USEPA). The USEPA defines an acceptable risk range to be an excess lifetime cancer risk (ELCR) between one (1) in ten-thousand (1.0E-4) and one (1) in one-million (1.0E-6) exposed. EHP has selected an acceptable risk to be defined as an ELCR of one (1) in one-hundred thousand (1.0E-5) exposed, consistent with past practices for a limited number of compounds that did not have ACGIH TLVs or RfCs to calculate AALs. The following section provides greater detail on the calculation of the proposed annual and 24-hour AALs.

Approach

1. Annual AAL

The EHP has calculated the probability of cancer from inhaling formaldehyde (annual AAL) by using the most recently updated toxicity factor identified in the USEPA's Regional Screening Level (RSL) tables (USEPA, 2020). This table identifies the USEPA Integrated Risk Information System (IRIS) inhalation Unit Risk (URi) factor for formaldehyde of 1.3E-5 µg/m^3 to evaluate cancer risk (USEPA, 1989). For this assessment, the EHP has assumed that receptors are exposed 24-hours per day, seven days per week for 30 years out of a life

expectancy of 70 years (USEPA, 2011). The following formula has been used to calculate the annual AAL:

$$C_{long} = \frac{ELCR}{(f_{life} \times URi)}$$

Where:

C_{long} = Annual AAL for formaldehyde in air (µg/m³)
ELCR = Excess lifetime cancer risk [1.0E⁻⁵]
f_{life} = Fraction of human lifetime over which exposure occurs (30 years exposure over 70 years of life)
URi = Unit risk inhalation factor (1.3E⁻⁵ µg/m³)

$$C_{long} = \frac{1.0E^{-5}}{\left(\frac{30\ yrs}{70\ yrs}\right) \times 1.3E^{-5}\mu g/m^3} = \mathbf{1.8\mu g/m^3}$$

2. 24-hour AAL

The USEPA Regional Screening Level (RSL) tables also identifies the Agency for Toxic Substances and Disease Registry (ATSDR) inhalation chronic minimum risk level (MRL) for non-carcinogenic endpoints. An MRL is an estimate of the amount of a chemical a person can breathe each day without a detectable risk to health. As a conservative measure, the EHP recommends adoption of the chronic MRL of 9.8 µg/m³ to represent the 24-hour AAL.

3. *De Minimis* Emission Levels

The annual and 24-hour *de minimis* emission levels have been calculated using these long-term and short-term risk based concentrations (RBC) using the formulas in Env-A 1410.03 and Env-A 1410.04 as follows:

- 24-Hour *De Minimis* level:

$$C\ lb/day = \frac{24 - Hr\ AAL}{84.17}$$

Where:

C lb/day = 24-hr De Minimis level
24-Hr AAL = 9.8 µg/m³
84.17 = Calculation factor to convert 24-Hr AAL to lb/day

$$C\ lb/day\ = \frac{9.8\,\mu g/m^3}{84.17}\ = \mathbf{0.12\ lb/day}$$

- Annual *De Minimis* Level:

$$C\ lb/yr\ =\ Annual\ AAL\ \times\ 16.28$$

Where:

C lb/yr = Annual De minimis level
Annual AAL = 1.8 µg/m³
16.28 = Calculation factor to convert Annual AAL to lb/yr

$$C\ lb/yr\ =\ 1.8\,\mu g/m^3\ \times\ 16.28\ =\ \mathbf{29\ lb/yr}$$

Conclusions and Recommendations

Exposure to concentrations of formaldehyde below these AALs are not expected to result in a significant human health risk pursuant to RSA 125-I:4,V and Env-A 1412.03(e)(2). Therefore, the EHP recommends the annual AAL, 24-hour AAL, and the *de minimis* emissions levels for formaldehyde be set as follows:

	***De Minimis* level**	**AAL (µg/m^3)**
24-Hour	0.12 lb/day	9.8
Annual	29 lb/yr	1.8

References

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