

FORMALDEHYDE

Comments on the **environmental sections** of the CEPA PSL Draft Assessment Report on Formaldehyde were provided by:

1. Alberta Environment
2. The Formaldehyde Council of Canada

Comments and responses are summarized below by Environment Canada. (All were based on the English version of the report).

| Comment ^(source) | Response |
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| <p>The definition of CEPA Toxic requires that the substance is entering or may enter the environment. As pointed out in the report secondary formaldehyde may contribute up to 70 – 90% of the total atmospheric formaldehyde. Most ambient formaldehyde is not entering the environment as required in the CEPA Toxic definition.⁽¹⁾</p> | <p>The definition of “substance” under CEPA 1999 is sufficiently broad to cover both direct release of formaldehyde into the environment and formation of formaldehyde in the environment by oxidation of natural and anthropogenic organic compounds present in air.</p> |
| <p>Section 2.3.2.4: These soil samples would have been taken from contaminated sites. Under normal conditions, concentration of formaldehyde in soil is much lower than the amounts quoted in the report.⁽¹⁾</p> | <p>Samples from contaminated sites were included but not used in assessing toxicity, as most exposure to biota is through air, and somewhat through water. Remote sites were reported as non-detectable.</p> |
| <p>What are the scientific justifications that the “Estimated No Effect Value” (ENEV) should be derived by dividing the “Critical Toxicity Value” (CTV) by a factor of 10 in the hyperconservative analysis and by a factor of 2 in the conservative analysis? In other PSL-2 assessments, rather than divided by a factor, the CTV is multiplied by an application factor to obtain the ENEV. These adjustments seem very much arbitrarily chosen.⁽¹⁾</p> | <p>A value of 10 is used in the hyperconservative analysis to account for high uncertainty in converting an effect concentration to a no-effect value, for variances in sensitivity between species and extrapolating laboratory data to field conditions.</p> <p>A lower value of 2 was chosen for the conservative analysis, as there is more certainty between field and laboratory data, and in extrapolations among plant species of the same genus. Also, a diverse data set permits a minimal application factor for interspecies extrapolation.</p> <p>Application factors were derived on a substance by substance basis, and were based on the quality of data sets, and amount of data.</p> |
| <p>Although formaldehyde involves in the reaction of tropospheric ozone formation, there were no analysis in the report to conclude that it is entering the environment in a quantity or</p> | <p>The analysis was based on a study produced in conjunction with a consultant, and based on the approach outlined in the Guidance Manual, which produced a high valued Photochemical</p> |

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| <p>concentration or under conditions that constitute or may constitute a danger to the environment on which life depends. There are a number of chemicals in the air that involve in the ozone chemistry and are of significant portions of the atmosphere, e.g. oxygen and methane, but are NOT CEPA toxic nor constitute a danger to the environment on which life depends. Furthermore, natural background ozone formation should produce more ozone than the amount produced by the 7.8% of the total volatile organic carbon reactivity contributions that come from formaldehyde.⁽¹⁾</p> | <p>Ozone Creation Potential. Both methane and oxygen have much higher concentrations in the atmosphere, and both are predominantly natural in origin.</p> <p>The 7.8 % of the total volatile organic carbon reactivity contributions that come from formaldehyde is a significant portion of the anthropogenic contribution. Formaldehyde is ranked as 4th among non-methane, carbonyl compounds that contribute to ground-level ozone.</p> |
| <p>Further documentation would be useful in order to support the “toxic” conclusion based on photochemical formation of ground-level ozone.⁽²⁾</p> <p>Management plans are being targeted at the minor industrial sources and not addressing the major automotive source.⁽²⁾</p> <p>A thorough review of all sources is needed before imposing more burdens on industry.⁽²⁾</p> <p>Concern about unwarranted monitoring of industrial uses of formaldehyde in resins, fertilizers and pulp and paper mills was expressed.⁽²⁾</p> | <p>In addition to the data provided in the Assessment Report, further evidence is available in the Supporting Document in support of the “toxic” conclusion.</p> <p>Management options for reducing releases will be addressed during the risk management phase. Key sources were identified as reaction product from vehicle exhaust (VOCs).</p> <p>A thorough review was undertaken during the assessment of this substance.</p> <p>Monitoring of secondary industrial sources is necessary to ensure that control measures for mobile sources are not compromised by new or increased releases from industry.</p> |

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Comments on the **health-related sections** of the CEPA PSL Assessment Report on formaldehyde were received from Alberta Environment and the Formaldehyde Council of Canada (FCC) and the Formaldehyde Epidemiology, Toxicology and Environmental Group, Inc. (FETEG). Members of FCC include Ashland Chemicals, ARC Resins Corp., BASF Canada Inc., Borden Chemical Inc., Canadian Council of Furniture Manufacturers, Composite Panel Association, Celanese Canada Inc., Georgia-Pacific, Louisiana-Pacific, Methanex Corp., Neste Chemicals, Ontario Furniture Manufacturers Association, Solutia Inc., Structural Board Association, Tembec Chemical, Uniboard, and West Fraser Mills Ltd. Members of FETEG include BASF, Borden Chemicals Inc., Celanese Ltd., Cytec Industries Inc., DuPont, Georgia-Pacific, Neste Resins Corp., and Solutia Inc. Individual comments have been summarized below.

To ensure transparency and defensibility in the timeframe mandated for completion of the assessments under CEPA, early submission of relevant data is encouraged and a cut-off date for their consideration specified. This ensures their appropriate consideration in the context of the complete identified database and full assessment through the several stages of internal and external review. Data submitted following the cut-off date are considered primarily in the context of establishing priorities for updating assessments in the strategic options/risk management phase or subsequently conducting full reassessments.

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| <p>The analysis of exposure to, and effects associated with, formaldehyde present in indoor air is not within the scope of CEPA.</p> | <p>In assessments of Priority Substances, exposure from all media in the general environment (including indoor air) is considered. Resulting recommendations are considered by relevant authorities as a basis for priority setting for risk management both under CEPA and under other Federal legislation and programs administered by Health and Environment Canada. This results in integrated assessment and consideration for control of the most important sources of human exposure.</p> |
| <p>FCC/FETEG expressed concern that formaldehyde is considered “toxic” under Paragraph 64c) based on its genotoxicity. They suggest instead that cytotoxic carcinogenesis be selected as the critical effect.</p> | <p>That genotoxicity is a contributing component in the carcinogenicity of formaldehyde is widely accepted and indeed, incorporated in the biologically-motivated case specific model developed by the Chemical Industry Institute of Toxicology, which FCC/FETEG “strongly</p> |

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| | support.” ¹ The approach adopted for formaldehyde is consistent with that of similarly acting carcinogens for which genotoxicity is a contributing component and is documented in the “ <i>Canadian Environmental Protection Act — Human Health Risk Assessment for Priority Substances</i> ” (Health Canada, 1994). |
| FCC/FETEG request that the Ministers revise the existing discussion of sensory irritation to eliminate the suggestion that the literature supports 0.1 ppm as a threshold level for this effect. | The Assessment Report does not suggest a definitive conclusion in this regard. Rather, it is reported that: “Though individual sensitivity and exposure conditions such as temperature, humidity, duration, and co-exposure to other irritants are likely to influence response levels, in well conducted studies, only a very small proportion of the population experiences symptoms of irritation following exposure to ≤ 0.1 ppm (≤ 0.12 mg/m ³) formaldehyde.” This is additionally qualified on the basis of less subjective effects measured at 0.3 mg/m ³ . These conclusions are consistent with those of a recent collaborative international effort addressing ambient air quality (WHO Air Quality Guidelines for Europe). The comments and supporting references (i.e., reviews of individual authors) submitted by FCC/FETEG in this context appear to reflect concern for potential implications for limits in the occupational environment, which is beyond the purview of assessments of Priority Substances. |
| FCC/FETEG suggest that the concentrations of formaldehyde in residential indoor air are very conservative, | These two studies were excluded from the estimates on the basis of the shortcomings identified in the Supporting Documentation. |

¹ FCC/FETEG advised that they strongly support the Ministers’ adoption of the CIIT Report” which they considered “reflects the most current and best available scientific information with respect to formaldehyde’s potential carcinogenicity”. In fact, owing to the lack of sensitivity analysis, quantitation of cancer risk based on the biologically-based case specific model developed by CIIT has been presented in the Assessment Report in only a supporting context as a basis to ensure that measures taken to prevent sensory irritation in human populations are sufficiently protective with respect to carcinogenic potential.

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| <p>due to the exclusion of two of the identified relevant studies. They further urge inclusion of these additional two studies or alternatively, an indication that the values for estimated exposure are very conservative.</p> | <p>In one case, it had not been demonstrated that a known and constant sampling rate of air was maintained during active sampling periods. In the other case, the analytical methodology was highly experimental and insufficiently validated with no demonstration of quality assurance for the sampling and analyses.</p> <p>The levels measured in the five studies included were internally consistent and similar to those reported in residential indoor air from studies conducted during comparable sampling and time periods in countries other than Canada. In view of the potential for less dilution of concentrations in air resulting from indoor sources in Canadian residential structures owing to lower average air exchange rates due to energy conservation than in warmer climates, the available data are considered representative rather than conservative.</p> |
| <p>FCC and FETEC indicate that the Draft Assessment Report should reference the U.S. EPA Home Study in its documentation.</p> | <p>Based on preliminary review of the report of the U.S. Home Study, there are no data contained therein which would impact on the essential content of the draft Assessment Report. The report describes a pilot study which could not be adequately completed due to time and budgetary constraints and numerous practical obstacles. Quantitative data included therein do not relate to exposure, <i>per se</i>, but rather to emissions from selected indoor sources (e.g., building products). If considered additionally informative, relevant information included therein relating source strengths, time varying concentrations and ventilation rates could be considered in the risk management phase.</p> |
| <p>FCC and FETEG indicated that the Draft Assessment Report should draw greater attention to the improvements made by the industry in products, manufacturing</p> | <p>Minor changes were made to Appendix C of the Supporting Documentation for the human exposure assessment to incorporate the information received. The citation</p> |

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| processes and to the high degree of industry compliance with voluntary standards established. | Liston (2000) was added to identify the source of this additional information. |