NSF review of "Incorporating use phase chemical leaching and water quality testing for life cycle toxicity assessment of cross-linked polyethylene (PEX) piping" as published in Science of the Total Environment (2021). Authors: Robert Phillips, Andrew J. Whelton, Matthew J. Eckelman.

This purpose of the study was to assess the phased leaching of TOC (total organic carbon) from PEX (cross-linked polyethylene) pipe over time and to relate this to life cycle toxicity.

PEX pipe samples certified to NSF/ANSI 61 were tested for TOC leaching over time periods of 3, 15 and 30 days. This data was extrapolated to estimate the lifetime TOC leaching and anticipated ingestion of TOC. Total organic carbon is a non-specific indicator of water quality. It measures total organic carbon that may include living and decaying matter as well as natural and synthetic chemical contaminants. Chemical analyses to identify specific contaminants were not conducted in this study. Instead, chemical contaminants identified in previous field studies of buildings with PEX piping were used to represent the contaminants that may be in the TOC leachates. Lifetime toxicity assessments were then calculated via the USETox model.

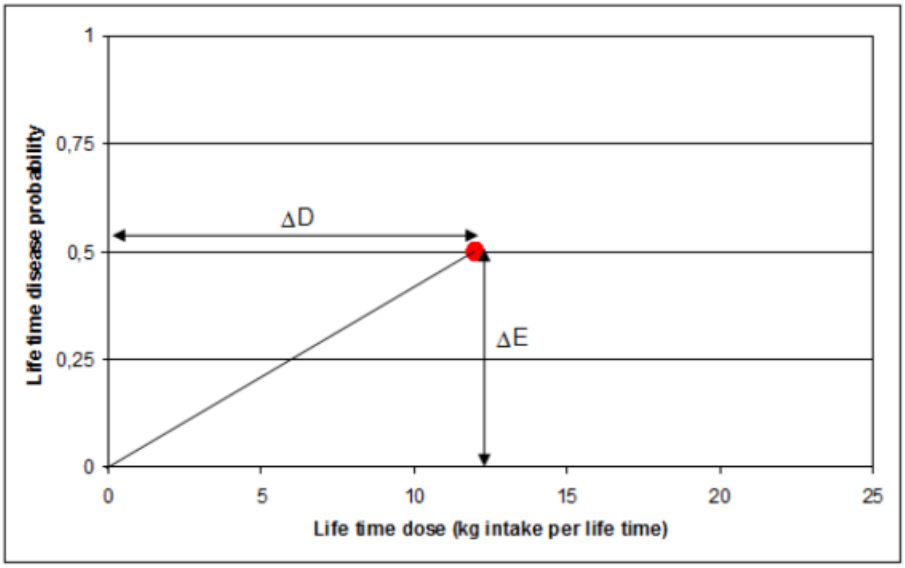
This study makes many assumptions that may not be valid.

- Chemical contaminants identified in the previously conducted field studies may have been from sources other than PEX pipe.
- Chemical contaminants from the field studies may not be in the piping products used in this study.
- Stagnant water time periods in actual occupied buildings may differ greatly from these studies, which used 3, 15 and 30 day time periods. This would impact the amount of chemicals that leach from the pipe and those that are assumed to be ingested.
- TOC leaching rates over time may not mimic the leaching of specific chemical contaminants.

Additionally, the USETox model used to calculate the potential human toxicity differs from the drinking water risk assessment approaches used by the USEPA and NSF/ANSI 61. The application of USETox for non-cancer effects is likely to be significantly overestimating risk when dealing with ppb (parts per billion) concentrations of contaminants. Even with that overestimation, the non-cancer risk values were actually quite low in the paper. Cancer effects were also reasonably low from the article with all samples but one below 10^-6 cumulative risk. This is also likely an overestimation since it attributed the TOC detection to each contaminant linked with cancer without knowing the true concentrations of each contaminant.

- USETox is intended as a screening-level model where its current LCIA (life cycle assessment impact) toxicity assessment assumes linearity for all dose-response models when assessing human toxicity (for both cancer and non-cancer effects). This assumption (linearity) ignores the possible existence of a threshold below which the chemical has no potential adverse effects and ascribes an adverse effect to any amount of chemical ingested.

- The key toxicity value for USETox is the human toxicological effect factor (EF) which reflects the change in lifetime disease probability due to change in lifetime intake of a pollutant (cases/kg intake). It is calculated under the assumption of linearity in concentration-response up to the point at which the lifetime disease probability is 50%. (See figure below).
- The Effect Factor (EF) is then multiplied against the total mass exposure of the chemical to estimate the health effect impact. Additivity of effects is assumed for both cancer and non-cancer effects to calculate a total risk.



- While U.S. EPA and NSF cancer risk assessments also follow linear approaches as a default (assuming a mutagenic mode of action), non-cancer risk assessments involve consideration of the dose-response curve in order to identify the point of departure for determining the reference dose (RfD) (See figure below)
    - USETox assumes any chemical exposure, regardless of dose, as contributing to overall risk and does not account for non-linear dose-response in assessing non-cancer toxicity (or non-mutagenic cancer endpoints).
- For USEPA (and NSF), the key toxicity value is the reference dose (RfD) which is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk.
    - RfD approach is utilized by US EPA, Health Canada as well as state health agencies in establishing drinking water limits
- The key point is that for non-cancer effects, USETox is very likely overestimating toxicity at the lower range of the dose-response due to the assumption of linearity compared to considering actual dose-response curves, which may indicate there is a threshold below which no adverse effects are occurring.
    - Given that we are typically dealing with low concentrations of contaminants leaching from products, the low dose region of the dose-response is the most critical region for drinking water contaminant risk assessments.

Other Toxicity Assessment Comments:

- Study author conservatively applied max effect (toxicity) factor to the entire TOC mixture to define upper bound of toxicity. This is very conservative as it assuming the entire mixture is comprised of the chemical with the worst-case Effect Factor
    - Again, the lack of product specific data is a severe limitation in this study as there is no certainty that the list of chemicals used for the toxicity assessment are associated with PEX or if found in PEX at what concentrations, which would allow for a more accurate assessment of toxicity.
- From the carcinogenicity evaluation of the "use phase" within the study, all but one sample were at or below a 10^{-6} risk level (1 excess cancer per 1 million people) suggesting overall low concern given the common use of 10^{-6} cancer risk levels to establish drinking water criteria
    - Lack of chemical specific extraction data is a significant limitation for the cancer assessment within the article.