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**Administrative considerations for setting a health based quality criterion and C-value (in Danish: B-værdi) for tetrachloroethylene in ambient air**

**Conclusion:**

The C-value at 0.01 mg/m3, Main Group 1 is maintained as an administrative limit value.

**Background**

Tetrachlorethylene was evaluated in 1995 and a health-based air quality criterion of 0.00017 mg/m3 was established based on the carcinogenic potential (liver tumours in mice) of tetrachloroethylene with the assumption of a non-threshold mechanism (genotoxicity) for the critical effect (Larsen 1995). The C-value (Contribution Value) was determined at 0.01 mg/m3, and tetrachloroethylene was placed in Main Group 1, which is the strictest regulation rate for emission.

In 2001, the documentation for tetrachloroethylene was updated and revised and the health-based air quality criterion was amended to 0.006 mg/m3 based on the toxicity to the liver, which is an endpoint assumed to have a threshold mechanism. The C-value remained at 0.01 mg/m3 and in Main Group 1. New evaluations of tetrachloroethylene as well as new data have subsequently been published since the revision in 2001 of tetrachloroethylene including:

SCHER Opinion (SCHER 2008),

US-EPA Toxicological Review (US-EPA 2012),

Focus of attention has also been to the genotoxicity study published in 2010 (Cederberg et al. 2010a). The new data was evaluated by the National Food Institute, Technical University of Denmark (DTU Food), who in 2013 proposed a new C-value on 0.05 mg/m3, Main Group 2 based on this.

**References:**

Nielsen E (2014): Evaluation of health hazards by exposure to tetrachloroethylene. Afdeling for Toksikologi og Risikovurdering, DTU Fødevareinstituttet. Baggrundsrapport udarbej­det for Miljøstyrelsen.

Subsequently concerns on prenatal and early postnatal neurotoxic effects have arisen, and resulted in an additional evaluation on this. The evaluation concluded that there was no association between the long-term prenatal and early postnatal exposure to tetrachloro-ethylene and the neurotoxic effects and the end points in the studies, and that the eased C-value also would take the prenatal and early postnatal neurotoxic effects into account.

**References:**

Gennemgang af 8 referencer vedr. tetrachlorethylens neurotoksicitet samt konklusion. Afdeling for Toksikologi og Risikovurdering, DTU Fødevareinstituttet. 06.10.2013

However the Steering Committee for Setting Quality criteria argued that there still are inconclusive concerns about the mentioned neurotoxicity of tetrachloroethylene and that robust data on this is lacking.

**Conclusion:**

The C-value at 0.01 mg/m3, Main Group 1 is maintained as an administrative limit value. DEPA decides to maintain the C-value, as there are inconclusive concerns about the neurotoxicity of tetrachloroethylene and as the data on this end point is doubtful at present and not sufficiently robust. Further the fact is that tetrachloroethylene is still listed as a possible carcinogen, nationally and internationally. The decision is acknowledged by the Steering Committee for Setting Quality criteria.