

Interpreting REACH guidance in the determination of the derived no effect level (DNEL).

Kreider, M.L. and E.S. Williams.

Abstract:

Under the new European chemicals regulation, REACH, a new safety value, the Derived No Effect Level (DNEL) must be established for all chemicals manufactured, imported or used in the EU in quantities greater than 10 metric tonnes per year. The DNEL is to be calculated for all relevant exposure pathways, exposure populations, and endpoints of toxicity. The EU has published guidance on how to derive the DNEL, but this guidance has yet to be put into practice and is in some places not prescriptive. Using the Agency for Toxic Substances and Disease Registry (ATSDR) dataset, we have determined inhalation DNELs for styrene. In doing so, we considered what effect key decisions would have on the calculated DNEL. The resulting DNELs were then compared to existing risk criteria values or occupational exposure limits. General population DNELs were generally more conservative than analogous risk criteria (ranging from approximately 0.05 to 2.5 ppm). Worker DNELs are lower than existing occupational standards (ranging from approximately 0.4 to 20 ppm). To our knowledge, this work represents the first rigorous application and interpretation of the EU guidance for determination of a DNEL and will prove useful as a model for determination of other DNELs under REACH.

Keywords: Occupational exposure limits, Risk characterization, DNEL, REACH, Styrene