

**Public Comment by JPEC:  
IRIS Toxicological Review of  
*Tert*-Butyl Alcohol [Tert-Butanol]  
(Public Comment Draft)**

IRIS Public Science Meeting  
*tert*-butyl Alcohol and BaP  
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On behalf of Japan Petroleum Energy Center, we submit the Public Comment as follows;

## **Regarding development of kidney tumors in male rats, rat-specific MOA cannot be ruled out**

- An increased severity of chronic nephropathy was observed at 2.5 mg/ml (230mg/kg bw/day) and above in male of the NTP 13-week drinking water study. Moreover, significant increased incidence of liner mineralization of renal papilla was observed at 1.25mg/ml(90mg/kg bw/day) and above in male rats of the NTP 2-year study. This lesion is specifically associated with nephropathy attributed to increased accumulation of  $\alpha_2u$ -globulin, which is rat specific.
- The severe chronic nephropathy induces renal tubular cell proliferation, resulting in induction of renal tumors.
- The thinking that this male rat carcinogenesis is not extrapolated to human is supported by regulatory agency of many countries.