

- A substantial body of information demonstrates that 2,3,7,8-TCDD is a potent carcinogen in laboratory animals. Much of the animal data indicates that 2,3,7,8-TCDD acts primarily (if not totally) as a promoter.
- There is a limited amount of epidemiologic information that suggests an association between certain types of human cancer and exposure to chemicals often contaminated with 2,3,7,8-TCDD. Independent analysis of these studies indicates that the differences between the control and "exposed" populations are real at some level. These studies suggest a potentially high human risk.
- There are also multiple epidemiologic studies in which no statistically significant association between possible exposure to 2,3,7,8-TCDD and cancer has been found. These studies suggest little or no human risk.
- There is a growing body of information that indicates that a number of people in the general population have low, measurable levels of 2,3,7,8-TCDD in their tissues. In most instances, the source of the 2,3,7,8-TCDD and the nature of the exposure (chronic, acute, high, low, recent, etc.) is unknown.
- However, at best there is only very limited information available on human metabolism of 2,3,7,8-TCDD (e.g., information on human half-life is based on one individual). Accordingly, while the information on human tissue levels of 2,3,7,8-TCDD is unquestionably a significant finding, use of that information to generate estimates about human exposure experiences and potential cancer risk is at this time, too speculative to be more than an academic exercise.
- There are multiple plausible explanations for the apparent discrepancies between the animal data and some of the human information. However, there are virtually no empirical data available that would allow us to identify the "truth".
- PAT'S BOTTOM LINE: In light of the above, it is reasonable for the Agency to acknowledge that there is a degree of uncertainty in its risk estimates (I think we all would agree on an order of magnitude range) and to emphasize that its estimates are upper limit numbers. To back away from the animal data (on which we rely in virtually all of our regulatory actions) and the seemingly positive human data without compelling evidence to support such a change is scientifically indefensible and asking for trouble on our regulatory decisions.