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# A CLASSIFICATION OF STATISTICAL APPROACHES TO EXPERIMENTAL CARCINOGENESIS

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**Abstract —** The interest in the assessment of cancer risk has led to various developments mainly based on biological basis and supported by statistical analysis. The aim of this paper is to discuss the bioassay of experimental carcinogenesis from a statistical point of view. Biological aspects (e.g., cell proliferation, mechanisms of inhibition in mutagenesis and carcinogenesis) of a cancer risk assessment are not taken up. The problem is viewed as a dose response problem and different models are assumed. In particular, several of the statistical models considered in the literature in the area of experimental carcinogenesis are discussed with an emphasis on dose dependent models. Moreover, an optimal experimental design approach for this particular bioassay is examined considering D – optimality as a design criterion and employing a stochastic method of approximation. Further, as the main problem in experimental carcinogenesis is the low – dose extrapolation and prediction due to the fact that animal experiments can not be applied directly to study low concentrations, an optimal sequential design approach is developed to estimate the parameter under investigation. Estimates of the appropriate percentiles of the risk function are obtained via simulation.

**Keywords and Phrases —** Experimental Carcinogenesis; Tolerance distribution models; Optimal designs; Stochastic approximation; Risk assessment.