SECTION I

GENERATION STUDIES

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One of the important problems of toxicity evaluation is the assessment of possible adverse effects of chemical compounds on unborn and future generations of human beings. Congenital malformations, both severe and trivial, are found in about 2-4% of all human births (1). Drugs and environmental chemicals are responsible for 2-3% of developmental defects in humans, but causes of 65-70% of these defects remain unknown (2). To protect human populations, the effects of substances newly introduced to industry must be assessed on animal reproduction. Such assessment is essential for compounds which may spread into the general environment in measurable amounts, which may have occupational contact with women of childbearing potential or which are used in drugs or as food additives. These chemicals may affect fertility and general reproductive performance, embryo and foetal growth and development and postnatal growth and functional maturation.

Fertility and General Reproductive Performance

Studies in this area attempt to provide the following information concerning the influence of chemicals: gonadal function of both males and females; the estrous cycle, mating behaviour, fertility and pregnancy rate, litter size, nursing behaviour and lactation of females; and the viability, growth and development of immature animals during weaning and puberty periods.

The multi-generation test was designed mainly for food additives and pesticide residues in food. However, it may be used to evaluate the effects of other environmental chemicals on general reproduction. Keplinger et al. (3) carried out studies of the effect of pesticides on reproduction in mice for six generations. Results indicate no basis for prolonging the tests for more than three generations. The so-called three-generation test requires that animals, usually rats or mice, be exposed continuously throughout three reproductive cycles. The test is performed on both females and males. The females may be mated with control (unexposed) and exposed males.