weight derived. Following removal, each foetus should be examined externally. For rats, mice and hamsters one-third to one-half of each litter should be prepared and examined for skeletal anomalies, and the remaining part of each litter should be prepared and examined for soft tissue anomalies using appropriate methods. For rabbits each foetus should be examined by careful dissection for visceral anomalies and then examined for skeletal anomalies.

## 3. DATA AND REPORTING

- Treatment of results

Data may be summarised in tabular form, showing for each test group the number of animals at the start of the test, the number which became pregnant, the number and percentages of live foetuses and foetuses with any soft tissue or skeletal abnormalities.

Whenever possible, all observed results should be evaluated by an appropriate statistical method. Any generally accepted statistical methods should be used; the statistical methods should be selected as part of the design of the study.

- Evaluation of results

The findings of a teratogenicity study should be evaluated in terms of the observed effects and the dose levels producing effects. It is necessary to consider the historical teratogenicity data on the species/strain tested. A properly conducted teratogenicity study should provide a satisfactory estimation of a no-effect level.

- Test report

The test report must include the following information:

- species/strain used;
- toxic response data by dose;
- time of death during the study or whether animals survived to termination;
- the time of observation of each abnormal sign and its subsequent course;
- food and body weight data;
- pregnancy and litter data; and
- foetal data (live/dead, sex, soft tissue and skeletal defects).

- Interpretation of the results

In the interpretation of the results of a teratogenicity study, species variation must be borne in mind. It should be realised that extrapolation of the results to man is valid only to a limited degree. However, the establishment of a no-effect level should enable appropriate protective measures to be taken.

## 4. LITERATURE

1. United States National Academy of Sciences, Committee for the Revision of NAS Publication 1138, *Principles and Procedures for Evaluating the Toxicity of Household Substances*, Washington, 1977.

2. Health Protection Branch, *The Testing of Chemicals for Teratogenicity, Mutagenicity and Carcinogenicity*. Ministry of Health & Welfare, Canada, 1977.

3. World Health Organisation. *Principles for the Testing of Drugs for Teratogenicity*, WHO Tech. Rep. No. 364, Geneva, 1967.