

APPENDIX A

Definitions

DEFINITIONS

Androgenic is a term used to describe a positive influence of a substance on the growth of androgen-dependent tissues.

Antiandrogenic is the capability of a substance to suppress the action of TP on the growth of androgen-dependent tissues in a mammalian organism.

Date of birth is postnatal day (pnd) 0.

Dosage is a general term comprising of dose, its frequency, timing and the duration of dosing.

Dose is the amount of test substance administered. For the Hershberger bioassay, the dose is expressed as weight of test substance per unit body weight of test animal per day (e.g., mg/kg body weight/day).

Evident toxicity is a general term describing clear signs of toxicity following administration of test substance. These should be sufficient for hazard assessment and should be such that an increase in the dose administered can be expected to result in the development of more severe toxic signs and probable mortality.

NOEL is the abbreviation for no-observed-effect level. In the Hershberger bioassay, this is the highest dose level where no statistically significant change in any androgen-dependent organ weight is observed due to treatment.

Positive and negative results for the castrate peripubertal male version of the Hershberger bioassay are defined as follows: A positive result is defined as the percent weights of at least four of the five androgen-dependent organs exhibiting statistically specific differences from the negative control mean values (vehicle control for androgenic evaluation; TP control for anti-androgenic evaluation).

Positive and negative results for the intact stimulated weanling of the Hershberger bioassay are defined as follows: A positive result for a test substance is defined as the mean weights of at least five of the six androgen-dependent organs exhibiting statistically specific differences from the negative control mean values (vehicle control for androgenic evaluation; TP control for anti-androgenic evaluation).

Postnatal day X is the Xth day of life after the day of birth.

Sensitivity is the capability of a test method to correctly identify chemicals having the property that is being tested for.

Validation is a scientific process designed to characterize the operational requirements and limitations of a test method and to demonstrate its sensitivity, specificity, reproducibility and relevance for a particular purpose.

Specificity is the capability of a test method to correctly identify chemicals not having the property that is being tested for.