In this chapter terminology and definitions are provided to give precise meaning to the terms that are used in this monograph. The use and meaning of terms employed in teratology studies vary between laboratories (Black and Marks, 1986) and regulatory agencies of different countries. An attempt to achieve worldwide uniformity in the assessment of human risks, particularly those involving prenatal and postnatal development, is an absolute need in view of rising international trade in foods, drugs, chemicals, and other regulated consumer products. Generally accepted terminology and definitions of key terms are necessary prerequisites for achieving such uniformity.

*Maternal toxicity* is a transitory or permanent pathologic state of health or alteration in maternal physiology and/or behavior with the potential to cause adverse effects in the offspring during embryofetal or postnatal development.

A *malformation* is a serious anatomical defect of prenatal origin that may or may not be compatible with survival. If compatible, it will adversely influence development, growth, morphology, physiological functions, fertility, and/or longevity.

An *abnormality* is an abnormal change in structure, appearance, function, or behavior. As distinct from a malformation, an abnormality does not influence postnatal development.

An *aberration* is a minor structural change. It may be a retardation (a provisional delay in morphogenesis), a variation (external appearance controlled by genetic and extragenetic factors), or a deviation (resulting from altered differentiation) (for details, see Khera, 1981).

A *teratogen* is an intrinsic or extrinsic factor or an alteration in maternal homeostasis that induces, during prenatal development, a permanent structural or functional abnormality in the fetus, which is detected in a prenatal or
postnatal examination (Clegg, 1971). If malformations are induced at apparently nonmaternotoxic doses, the agent is a true, or selective, teratogen.

**Embryotoxicity** signifies embryonic loss during the early preimplantation or postimplantation stages of pregnancy.

**Fetotoxicity** is any prenatally initiated toxic manifestation observed in a fetus (death, body-weight reduction, delayed ossification, or functional defect), which may or may not be related to toxic effects in the mother and which although initiated in utero appears during prenatal or postnatal development. Any of these effects resulting from the direct action of a test agent on the embryo or fetus (as defined in *Dorland's Medical Dictionary*) and occurring at doses far below those toxic for the mother should be regarded as suggestive of true, or selective, embryo- or fetotoxicity.

The term *embryo-fetus* is used when the stage of prenatal development at the time of initial insult is not known.

**Developmental toxicity** represents any adverse effect on development (morphologic, physiologic, or functional) initiated prenatally and appearing during the lifetime of the progeny.

**Reproductive toxicity** deals with toxic effects on any aspect of reproduction of offspring proceeding from the development of gametes and their fusion.

A **threshold level** is the highest level of a chemical or test substance, obtained by the best possible estimates from experimental data, that is judged insufficient to produce an adverse effect on prenatal and postnatal development in humans or animals.

A **safety factor** is an arbitrarily determined numerical value that allows for the uncertainty in estimating potential human effects from animal data and for unforeseen individual sensitivity in the human population. An acceptable dose is derived from the maximum dose at which no adverse effects are observed divided by a safety factor (WHO, 1958).

**Reproductive hazard** is the likelihood that a chemical or test substance will cause an adverse effect, including gross anatomical defects, on any aspect of reproduction under the conditions of its production or use (modified from WHO, 1978).

**Risk** is the expected frequency of undesirable effects arising from a given level of exposure to a chemical or test substance. An acceptable risk is based on the probability of occurrence of adverse effects and their consequences on human health compared with the benefits from the use of a substance.

**Safety** is the practical certainty that an adverse effect will not result when a substance is used in the proposed quantity or manner.

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**References**