10.0 ANIMAL WELFARE CONSIDERATIONS (REFINEMENT, REDUCTION, AND REPLACEMENT)

10.1 How the ICE Test Method Will Refine, Reduce, or Replace Animal Use

ICCVAM promotes the scientific validation and regulatory acceptance of new methods that refine, reduce, or replace animal use where scientifically feasible. Refinement, Reduction, and Replacement are known as the "Three Rs" of animal protection. These principles of humane treatment of laboratory animals are described as:

- refining experimental procedures such that animal suffering is minimized
- reducing animal use through improved science and experimental design
- replacing animal models with nonanimal procedures (e.g., *in vitro* technologies), where possible (Russell and Burch 1992)

The ICE test method refines animal use. Since these animals are being humanely killed for non-laboratory purposes, there is no additional infliction of animal pain or distress caused by the testing procedure. Furthermore, substances that are identified as corrosive or severe irritants *in vitro* would be excluded from *in vivo* testing, thus sparing rabbits from the pain associated with these types of substances.

The ICE test method can also reduce animal use through two different mechanisms. The ICE test method was adapted from the IRE test method in order to use an animal species routinely raised as a food source in large numbers to replace the need for laboratory animals. Additionally, with the acceptance of a positive outcome (i.e., classification of a substance as a severe ocular irritant) from the *in vitro* method, the animals that would have been used in the *in vivo* rabbit eye test would be spared.

10.2 Requirement for the Use of Animals

Although chickens are required as a source of corneas for this organotypic *in vitro* assay, only chickens humanely killed for food or other non-laboratory purposes are used as eye donors (i.e., no live animals are used in this assay).

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