

10.0 □□□ ANIMAL WELFARE CONSIDERATIONS

10.1 How the IRE 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 IRE was initially developed as an organotypic, *in vitro* assay for the detection of severe eye irritants to avoid the testing of such substances in live animals (Burton et al. 1981). The IRE test method reduces animal use when eyes are obtained from rabbits raised for food or by obtaining them from rabbits sacrificed after use in other laboratory procedures that do not adversely affect the eye. The IRE test method is a refinement of the *in vivo* rabbit eye test in that the animals are sacrificed prior to application of the test substance and, therefore, the animals do not experience pain and suffering when an ocular irritant is directly applied to the eye. Furthermore, since the IRE test method was adapted from the Draize *in vivo* eye irritation test method specifically to reduce the need for live animals for ocular irritation testing, pain and suffering of the animals is eliminated and the overall number of animals needed for ocular toxicity screening is reduced.

10.2 Requirement for the Use of Animals

Although rabbits are required as a source of corneas for this organotypic assay, only rabbits sacrificed for food or used for other laboratory purposes are typically used as eye donors (i.e., no live animals are used in this assay).

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