

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

10.1 How the BCOP 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)

With respect to these animal welfare considerations, the BCOP assay both refines and reduces the use of laboratory animals bred specifically for the purpose of toxicity testing. This assay uses isolated corneas from cattle that have been slaughtered for the food industry or for other nonlaboratory purposes. Since isolated tissues are treated in the assay, treatment-related pain and suffering are avoided in live animals. By using slaughterhouse by-products, the BCOP assay also reduces the use of laboratory animals (i.e., substances that are identified as ocular corrosives or severe irritants *in vitro* would be excluded from testing *in vivo*).

10.2 □□□ Requirement for the Use of Animals

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

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