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Current Status and Future Considerations for Alternative Methods to Refine, Reduce, and Replace Animal Use for Ocular Safety Testing

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The original and modified Draize rabbit eye tests have been used for over 60 years to identify potential acute ocular hazards of chemicals and products. Such testing has been highly effective in safeguarding human health by identifying and classifying potential ocular hazards. Nevertheless, public animal welfare concerns and a European law banning the use of this test for cosmetics testing no later than 2009 have led to significant efforts during the past 20 years to develop and validate *in vitro* tests to replace animals for ocular testing. While there is still no valid replacement for the Draize eye test, new testing guidelines now allow for the use of valid and accepted *in vitro* test methods in a tiered testing strategy. When animals are needed, such determinations can now be made with only 1-3 animals. The proposed tiered testing strategy provides for stepwise weight-of-evidence hazard decisions to be made based on existing data, structure activity/property relationship evaluations, *in vitro* data, and/or data from other *in vivo* testing. Topical anesthetics are also now permitted to reduce or avoid animal pain, provided that there is no interference with the outcome of the study. Future *in vitro* test methods and/or test batteries proposed to completely replace the *in vivo* test will require adequate validation and will need to accurately identify ocular irritants and corrosives, especially those that may cause permanent visual impairments. Appropriate reference chemicals with high quality *in vivo* data will be necessary to assess the performance of these new tests. Progress in refining, reducing, and replacing animal use for ocular toxicity is expected as tiered testing strategies are implemented, and existing and new mechanism-based test methods are validated and accepted.

SOT Itinerary Information:

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Session:	Current Status and Future Considerations for the Development and Validation of <i>In Vitro</i> Alternatives to the Draize Rabbit Eye Test