

MEETING OF THE SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

People for the Ethical Treatment of Animals
and
Physicians Committee for Responsible Medicine

September 2, 2015



PETA and PCRM

Global harmonization

- Funding research & validation studies for promising non-animal tests
- Regulatory acceptance & implementation of alternatives to animal test methods
- Outreach & public education about non-animal test methods



Federal Agency Updates

Timely acceptance of new methods and relevant revision of guidance documents

- Skin sensitization
- Draize test
- FDA CFSAN's updates to the Redbook
- EPA OPPT



Federal Agency Updates

Regular training opportunities for reviewers and inspectors at regulatory agencies



Federal Agency Updates

Update and progress toward achieving NICEATM / ICCVAM workshop recommendations

- CVB Notice 12-12

This Notice informs licensees, permittees, and applicants of current Center for Veterinary Biologics (CVB) policy concerning the use of humane endpoints in animal challenge tests and the use of anesthesia before and during intracerebral (IC) inoculation. It confirms CVB's commitment to replacing, reducing, and refining animal use.

The CVB encourages the use of analgesics in animal studies and potency testing, when it can be shown this does not affect the study outcome.

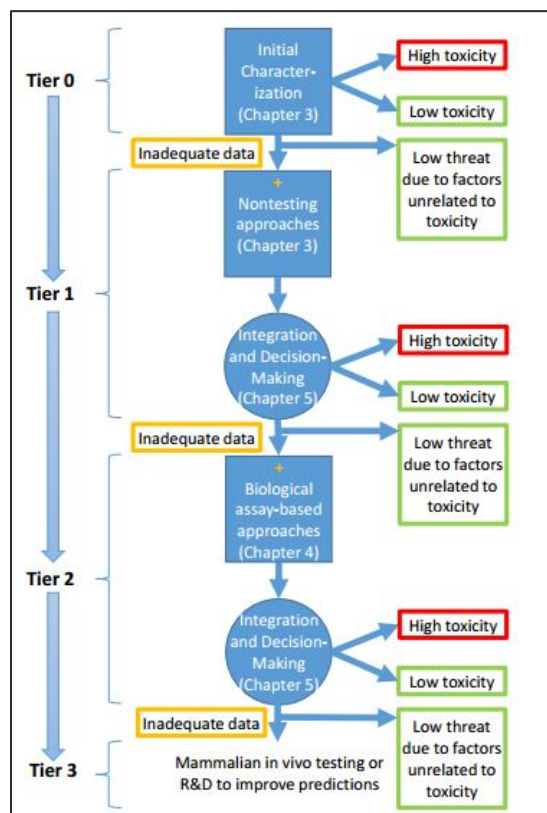
- Other workshop updates



Federal Agency Updates

Acute systemic toxicity testing

- From the DoD-commissioned NAS report “Application of Modern Toxicology Approaches for Predicting Acute Toxicity for Chemical Defense”.



Federal Agency Updates

In vitro botulinum toxin detection method development



Metrics, Measuring Success in the 3Rs

Tracking the number of mice and rats

- See Goodman, Chandna, and Roe. Trends in Animal Use at U.S. Research Facilities. *Journal of Medical Ethics*. 2015;41:7 504-505
 - “These data show a statistically significant 72.7% increase in the use of animals at these US facilities...”

Tracking the use of alternative methods for biologics testing

