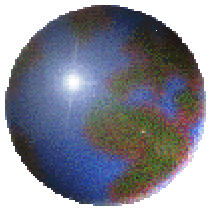

ELIMINATING ANIMAL TESTING OF ANTIMICROBIAL FORMULATIONS

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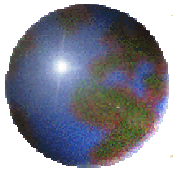

Animal Alternatives – Historical Perspective

- Much research has been conducted on developing non-animal approaches to evaluating toxicity.
- Many methods exist, but few have undergone formal validation.
- Many times lack of validation is based on lack of data.
- Validation is needed for broad acceptance of any method.

Formulation Testing Under FIFRA

- Animal testing for skin and eye irritation is required in order to register an anti-microbial formulation.
- Alternative methods exist today for these endpoints.
- These methods have not undergone formal validation and therefore EPA is limited in their ability to accept them.

Validation of Alternatives for Eye and Skin Irritation

- ICCVAM and ECVAM are in the process of evaluating alternative methods for skin and eye irritation.
- Goal of validation will be to seek broad replacement of the current animal methods.
- Many alternative methods give a yes/no answer as opposed to data that can be used for labeling decisions.
- Timing and success of current validations are uncertain.

Path Forward

- A non-animal risk assessment approach exists today for evaluating the skin and eye irritation of antimicrobial formulations.
- While continuing to wait for broad-scale validation of alternative methods, let's go forward today with a sector-specific validation for which supporting data are available and validation is assured.

Recommendation

- It is recommended that a non-animal risk assessment approach for evaluating the skin and eye irritation of formulations regulated by the Antimicrobial Division of EPA be developed and validated.

Next Step – Alternatives Workshop

- Experts in animal alternatives for skin and eye irritation will gather to agree on the non-animal risk assessment approach.
- These experts will do three things:
  - Define the formulation types to be included.
  - Agree on the appropriate test methods to evaluate toxicity and define labeling.
  - Write a workshop summary that outlines the conclusions.

Next Step – Peer Review/Validation

- The product of the Alternatives Workshop will be submitted to ICCVAM for an independent review. The goal would be their agreement to the technical robustness of the non-animal risk assessment approach.

Next Steps - EPA

- Once the workshop is successfully completed, EPA will write an interim policy accepting the non-animal approach for the defined formulation types.
- Once the ICCVAM review is successfully completed, EPA will make that policy permanent.

Where Do We Go From Here?

- Collaborative effort by EPA, ICCVAM and stakeholders to go forward with this recommendation.
- Formation of a subgroup of interested parties to formally define goals and expectations, determine if sectors other than antimicrobials should be included, and plan the workshop.