USEPA’s Office of Pesticide Programs

Update on Animal Reduction & Implementing Alternatives
Inhalation Risk Assessment


Thursday, March 14, 8:30 AM to 11:15 AM in the Workshop Session: Use of Adverse Outcome Pathways to Design Nonanimal Testing Strategies for Assessing Inhalation Toxicity

• Proposal for refining inhalation risk assessment using a 3D human airway epithelia reconstituted in vitro model initially presented to EPA in 2014 by Syngenta Crop Protection

• Agency recognized the value of the proposal for chlorothalonil, as well as other respiratory contact irritants and encouraged further development

• Collaborated with National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) for review

• Convened FIFRA SAP meeting in December 4-7, 2018 to evaluate the proposed approach
  • First time a point of departure for risk assessment will be derived using in vitro data for a pesticide
  • Potential use for other contact irritants, as well as other chemicals that cause portal of entry effects in the respiratory tract

• SAP report expected in April, 2019
Developing guidance and waiver approach for rodent carcinogenicity studies

Commitment at the US EPA/OPP to Reduce and Replace Animal Use: Looking at Carcinogenicity and Beyond. G. Akerman. US EPA, Washington, DC.

Monday, March 11, 1:45 PM to 4:30 PM in the Workshop Session: A Herculean Switch? Rethinking Chemical Carcinogenicity Assessment

- EPA-OPP is currently collaborating with industry and non-government organizations
- Workgroup is considering:
  - Different chemistries
  - Modes of action
  - Use patterns/exposures
  - Metabolic profiles
- Goal: Develop waiver criteria for rodent carcinogenicity studies.
Modernizing Acute Toxicity “6 Pack”


Tuesday, March 12, 1:00 PM to 2:30 PM in the Symposium Session: Scientific and Regulatory Update in the Application of the 3Rs Principle in Chemical and Drug Development


Wednesday, March 13, 8:00 AM to 10:45 AM in the Symposium Session: Establishing Effective Alternatives for Acute Oral and Inhalation Systemic Toxicity Testing

- Letter to Stakeholders on OPP’s Goal to Reduce Animal Testing from Jack E. Housenger, Director.
  - [https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2016-0093-0003](https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2016-0093-0003)
  - Working in partnership with other governmental entities, industry and non-governmental organizations (NGOs) and need continued robust participation and support to achieve our mutual goal.
  - Activities fall under three main objectives
    - Critically evaluating which studies form the basis of OPP decisions;
    - Expanding acceptance of alternative methods and;
    - Reducing barriers such as challenges of data sharing among companies and international harmonization to adopting alternative methods in the U.S. and internationally.
Draft Interim Science Policy: Use of Alternative Approaches for Skin Sensitization as a Replacement for Laboratory Animal Testing

• Announced April 10, 2018 & describes the science that supports a policy to accept alternative (in vitro, in silico, in chemico) approaches for identifying skin sensitization hazard in place of animal studies.

  • **Multiple non-animal testing strategies - in vitro, in chemico, and in silico inputs demonstrate comparable or superior performance to the laboratory animal studies.**

• The interim policy is the result of collaboration between
  • Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
  • NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)
  • European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)
  • Health Canada (PMRA)
Retrospective Analysis: Avian Subacute/Acute Risk

Monday, Author Attended: 3:00 PM–4:30 PM Poster Board Number P183

• Background
  • 40 CFR Section 158 outlines two requirements for avian acute effects testing
    • Two single oral dose LD50 studies (commonly quail or mallard and a songbird)
    • Two subacute dietary LC50 studies (commonly quail and mallard)
  • Can we confidently assess acute risk for birds using a reduced suite of effects studies focusing on the single oral dose protocol?
    • How often have subacute dietary risk quotients (RQs) quantitatively driven risk assessment conclusions?
    • How often have subacute dietary risks qualitatively altered the risk conclusions?
  • Bottom Line: In 99% of cases (118 of 119) the subacute dietary approach did not change risk conclusions already reached using oral, dose-based RQs
  • Peer-reviewed scientific journal publication (PETA lead, Agency coauthors): manuscript has been submitted
EPA-OPP is hiring toxicologists !!!

• Interested? Stop by the EPA ORD Booth (#4065)

• EPA-OPP representatives will be there:
  Monday 1:30-2:30
  Tuesday 2:30-3:30
  Wednesday 10:30-12:00

USAjobs announcement#:
09/11 is R-OCSPP-DE-2019-0036
12/13 is R-OCSPP-DE-2019-0037