Beyond the 6-pack: Strategic Roadmap Future Priorities

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National Institutes of Health • U.S. Department of Health and Human Services
• Guidance/policy docs within and across agencies
  – Public/Private partnerships

• International harmonization
  – OECD guidelines and/or IATA case studies

• Education/training
  – Role of NGOs and industry consortiums

“OPP’s immediate goal is to significantly reduce the use of animals in acute effects testing (the “6-pack” studies). Over 50 animals are used for a complete set of 6-pack studies. Annually, we receive over 500 acute toxicity 6-pack submissions.”

March 2016 letter to Stakeholders from Jack Housenger on the goal to reduce animal testing
Extending beyond single chemicals

- Application to mixtures (e.g. pesticide formulations, medical device extracts)
  - Data sharing across industry
  - Generating data with Defined Approaches
  - GHS Additivity Approach
• Defining agency- and endpoint- specific contexts of use
  – Prioritizing NAM development/validation accordingly

• Focus on more complex endpoints
  – DTT partnerships: DNT, Cardiotoxicity, Carcinogenicity
  – Systemic toxicity
  – Others?

• Improving environmental health protection
  – Addressing population variability and susceptibility
  – Further developing protective, probabilistic NGRA approaches
  – Providing rapid response options
An in-person workshop to examine the state of the science for NAMs modeling the gastrointestinal tract and their context for regulatory consideration.

- **Focal Areas:**
  - General “state of the science” for NAM gut models
  - Models for de-risking chemicals for systemic toxicity (regulatory relevance and application)
  - Gastrointestinal toxicity
  - Systemic absorption and distribution
  - Gut allergenicity
  - Breakout groups covering the following themes:
    - Establishing confidence in existing models
    - Strengths and limitations of different model systems

- **Webinar series to provide background information**
  - September 18, 9:00 am – 10:00 am EDT
  - September 20, 9:00 am – 10:00 am EDT
  - October 6, 9:00 am – 10:00 am EDT
Acknowledgments

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