OPP Progress on Reducing Animal Testing & Adopting Alternative Methods Update
October 28-29, 2020 Pesticide Program Dialogue Committee Meeting

On September 10, 2019, EPA Administrator Andrew Wheeler signed a directive that prioritizes efforts to reduce animal testing (https://www.epa.gov/sites/production/files/2019-09/documents/image2019-09-09-231249.pdf). The memorandum calls for the agency to: reduce its requests for, and funding of, mammal studies by 30 percent by 2025, and eliminate all mammal study requests and funding by 2035. Any mammal studies requested or funded by EPA after 2035 will require administrator approval on a case-by-case basis. As a result of the directive, a New Approach Methods plan was released in June 2020 (https://www.epa.gov/chemical-research/epa-new-approach-methods-work-plan-reducing-use-animals-chemical-testing). This work plan was developed by agency experts including members of OPP. Further, EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and Office of Research and Development (ORD) hosted the Second Annual Conference on the State of the Science on Development and Use of New Approach Methods (NAMs) for Chemical Safety Testing. The conference was held virtually October 19-20, 2020 (https://www.epa.gov/chemical-research/second-annual-conference-state-science-development-and-use-nams-chemical-safety-0#1).

OPP continues to make progress towards reducing laboratory animal use. February of 2020 marked the release of the *Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis.* The new guidance allows certain avian toxicity studies to be waived for outdoor pesticide registrations when the agency has sufficient information on the acute oral risks for birds. The adoption of the guidance is expected to reduce the number of birds tested by approximately 720 per year (https://www.epa.gov/sites/production/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf). In July 2020, OPP released its *Fish Bioconcentration Data Requirement: Guidance for Selection of Number of Treatment Concentrations* that provides recommendations reducing the number of required concentration levels used in BCF testing from three to two. The adoption of this guidance is expected to reduce the number of test animals by approximately 240 per year (https://www.epa.gov/sites/production/files/2020-07/documents/bcf-study-july-15-2020.pdf).

This month, OPP released the proposed draft Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Technical Chemicals & Supporting Retrospective Analysis to expand the potential for data waivers of dermal lethality studies beyond end use formulations to single active ingredients. This Guidance is based on a retrospective analysis conducted by EPA and NICETAM which determined the acute dermal lethality study provided little to no added value in regulatory decision making. This Guidance is expected to save up to 750 animals annually. EPA will take comments on the proposed guidance through November 9, 2020. Comments can be submitted online at https://www.regulations.gov (Docket ID No. EPA-HQ-OPP-2016-0093). After carefully considering public input, EPA will finalize the Guidance. Lastly, EPA has launched a new webpage that highlights strategies for reducing and replacing animal testing in pesticide risk assessment, as well as, metrics to quantitatively measure the success of these initiatives (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/strategic-vision-adopting-new-approach-methodologies).

In June 2020, OPP, in collaboration with government, non-government and industry stakeholders, presented the status of several on-going projects related to new approach methods and reducing the use of laboratory animals for chronic and carcinogenicity testing to the Science Advisory Board (SAB). EPA's white paper and the SAB consultation report can be found at: https://yosemite.epa.gov/sab/sabproduct.nsf//LookupWebProjectsCurrentBOARD/2D3E04BC5A34DCDE8525856D00772AC1?OpenDocument. In September 2020, OPP convened a meeting of the Federal Insecticide, Fungicide and Rodenticide Act Scientific Advisory Panel (SAP) on activities related to

alternative methods that could inform human health risk assessment for organophosphate pesticides and reduce animal testing for developmental neurotoxicity in the future. A report from the panel is expected in December 2020 (https://www.epa.gov/sap/use-new-approach-methodologies-nams-derive-extrapolation-factors-and-evaluate-developmental).