



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 10, 2019

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Directive to Prioritize Efforts to Reduce Animal Testing

FROM: Andrew R. Wheeler
Administrator

A handwritten signature in black ink, appearing to read "Andrew Wheeler".

TO: Associate Deputy Administrator
General Counsel
Assistant Administrators
Inspector General
Chief Financial Officer
Chief of Staff
Associate Administrators
Regional Administrators

During my March 2019 all-hands address, I reiterated the U.S. Environmental Protection Agency's commitment to move away from animal testing. We are already making significant efforts to reduce, replace and refine our animal testing requirements under both statutory and strategic directives. For example, the *Toxic Substances Control Act*, amended June 22, 2016, by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires the EPA to reduce reliance on animal testing. Also, Objective 3.3 of the *FY 2018-2022 U.S. EPA Strategic Plan* outlines a commitment to further reduce the reliance on animal testing within five years. More than 200,000 laboratory animals have been saved in recent years as a result of these collective efforts.

Scientific advancements exist today that allow us to better predict potential hazards for risk assessment purposes without the use of traditional methods that rely on animal testing. These new approach methods (NAMs), include any technologies, methodologies, approaches or combinations thereof that can be used to provide information on chemical hazard and potential human exposure that can avoid or significantly reduce the use of testing on animals. The benefits of NAMs are extensive, not only allowing us to decrease animals used while potentially evaluating more chemicals across a broader range of potential biological effects, but in a shorter timeframe with fewer resources while often achieving equal or greater biological predictivity than current animal models.

To aggressively pursue a reduction in animal testing, I am directing leadership and staff in the Office of Chemical Safety and Pollution Prevention and the Office of Research and Development to prioritize ongoing efforts and to direct existing resources toward additional activities that will demonstrate measurable impacts in the reduction of animal testing while ensuring protection of human health and the environment. I am also directing all EPA Assistant Administrators to identify additional opportunities within their programs where we can take accountable steps to significantly reduce the number of animals used in testing. This includes finding new ways to leverage our existing partnerships into continued success and scientific achievements. Where new cross-office activities are identified, additional agency resources may be activated to support these efforts.

I am pleased today to establish the following commitments that will ensure our work in this area makes a real and significant difference. The EPA will reduce its requests for, and our funding of, mammal studies¹ by 30 percent by 2025 and eliminate all mammal study requests and funding by 2035. Any mammal studies requested or funded by the EPA after 2035 will require Administrator approval on a case-by-case basis. The EPA also will come as close as possible to excluding from its approval processes any reliance on mammal studies conducted after January 1, 2035, including those performed by third parties, subject to applicable legal requirements, including the *Administrative Procedure Act*.

My senior leadership team immediately will form a working group of agency experts in this field who will provide a work plan to me within six months. This plan will identify tangible steps to ensure that the agency's regulatory, compliance and enforcement activities, including chemical and pesticide approvals and agency research, remain fully protective of human health and the environment while pursuing these reduction goals. This plan will include:

1. Validation to ensure that NAMs are equivalent to or better than the animal tests replaced;
2. Demonstration that NAMs are applicable for use in risk assessment and that new decision-making approaches are as protective of human health and the environment as existing approaches;
3. Recognition that statutory and regulatory requirements for animal testing currently exist and that a plan to adopt more flexible requirements should be developed;
4. Outreach to all stakeholders to incorporate their knowledge and address concerns; and
5. Establishment of baselines, measurements and reporting mechanisms to track the agency's progress.

I also request that OCSPP and ORD hold a joint annual conference on NAMs, with the first conference to be held in 2019. These conferences will provide a forum for presentations by leading scientists in the NAMs field. Summary reports from the annual conferences will serve as an important resource on NAMs developments to scientists and policy makers.

During the past several years, OCSPP and ORD have worked together to make significant progress to reduce, replace and refine animal testing requirements. Beginning in 2012, the Endocrine Disruptor Screening Program began a multi-year transition to validate and more

¹ This applies to whole animal or live mammalian studies and does not apply to use of mammalian cell cultures or human epidemiological studies.

efficiently use computational toxicology methods and high-throughput approaches that allow the EPA to more quickly and cost-effectively screen for potential endocrine effects. In 2017 and 2018, ORD and OCSPP worked with other federal partners to compile a large body of legacy toxicity studies that was used to develop computer-based models to predict acute toxicity without the use of animals. In June 2018, the EPA released the *Strategic Plan to Promote the Development and Implementation of Alternative Test Methods with the TSCA Program*², which includes strategies to reduce, refine or replace vertebrate animal testing as required under the amended TSCA. Through its ongoing research, ORD has made substantial progress and is an international leader in advancing the development of NAMs for filling information gaps for decision-making, integrating data streams into chemical risk assessment to inform work within the program offices and making the information publicly available through online tools like the CompTox Chemical Dashboard.

OCSPP is also focused on application of alternatives, such as those developed with ORD and other federal partners, for replacing pesticide acute toxicity testing. By working together with stakeholders on alternatives for acute toxicity testing, the EPA has saved thousands of animals used in laboratory testing annually, while at the same time ensuring the protection of human health and the environment. From December 2011 to May 2018, the EPA deferred more than 1,000 pesticide toxicity studies under its Federal Insecticide, Fungicide, and Rodenticide Act waiver process, saving more than 200,000 laboratory animals and reducing costs to the pesticide industry by more than \$300 million dollars while maintaining confidence in the EPA's scientific conclusions.

EPA staff have also been working collaboratively with a wide range of stakeholders to achieve these efforts, including international and federal agencies, the regulated community, animal welfare groups and other non-governmental organizations. The Interagency Coordinating Committee for the Validation of Alternative Methods, comprised of the EPA and 15 other federal regulatory and research agencies, and the National Toxicology Program Interagency Center for the Evaluation of Alternatives Toxicological Methods have been instrumental in facilitating and supporting the development, validation and acceptance of alternative test methods across federal agencies.

I am pleased with this progress, but I know that the EPA can and should do more. Development of NAMs is critical to the long-term successful implementation of the Lautenberg Act and the agency's overall mission. Animal testing is expensive and time-consuming. The agency must develop more accurate, quicker and more cost-effective test methods if it is to meet its 21st century commitments. We must make that investment now.

With this memorandum I am charging all agency leaders to take actions consistent with this vision and to elevate our efforts to the next level. Through scientific innovation and strategic partnerships, we can protect human health and the environment by using cutting-edge, ethically sound science in our decision-making that efficiently and cost-effectively evaluates potential effects without animal testing. These goals are far from mutually exclusive, and I am confident that with partnerships, focus and the directives outlined above, we will continue to achieve our mission to protect human health and the environment.

² https://www.epa.gov/sites/production/files/2018-06/documents/epa_alt_strat_plan_6-20-18_clean_final.pdf