Message

From: Graff, Jaimie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31BF142AF8114EFCA4D2E2E1DD7C489C-GRAFF, JAIMIE]
Sent: 12/6/2021 2:58:53 PM
To: Ware, Michael [Ware.Michael@epa.gov]
Subject: RE: EPA animal testing targets

Tracking for all sites is going to be very interesting.
J

From: Ware, Michael <Ware.Michael@epa.gov>
Sent: Monday, December 6, 2021 9:58 AM
To: Graff, Jaimie <Graff.Jaimie@epa.gov>
Subject: RE: EPA animal testing targets

That makes sense to include all vertebrates

Mike

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ware.michael@epa.gov

From: Graff, Jaimie <Graff.Jaimie@epa.gov>
Sent: Monday, December 6, 2021 9:53 AM
To: Ware, Michael <Ware.Michael@epa.gov>
Subject: RE: EPA animal testing targets

Thank you.
I knew some changes were coming.
Be aware that while the specific years were stripped out, the emphasis on what kind of animals would be under scrutiny has shifted from just mammals to all vertebrates.
Expect to see things about that sometime in the not too distant future.
J

From: Ware, Michael <Ware.Michael@epa.gov>
Sent: Monday, December 6, 2021 9:49 AM
To: Graff, Jaimie <Graff.Jaimie@epa.gov>
Subject: RE: EPA animal testing targets

https://insideepa.com/sites/insideepa.com/files/documents/2021/dec/epa2021_2279.pdf

looks like this is link to the report

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From: Graff, Jaimie <Graff.Jaimie@epa.gov>
Sent: Monday, December 6, 2021 9:47 AM
To: Ware, Michael <Ware.Michael@epa.gov>
Subject: RE: EPA animal testing targets

This one is a little different, since it's emails, correspondence, etc., not just reports.
J

From: Ware, Michael <Ware.Michael@epa.gov>
Sent: Monday, December 6, 2021 9:30 AM
To: Graff, Jaimie <Graff.Jaimie@epa.gov>
Subject: RE: EPA animal testing targets

BTW when aren't you dealing with a FOIA request?

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From: Graff, Jaimie <Graff.Jaimie@epa.gov>
Sent: Monday, December 6, 2021 9:22 AM
To: Ware, Michael <Ware.Michael@epa.gov>
Subject: RE: EPA animal testing targets

What is the source for this report?
FWIW, we're also being FOIA'd right now.
J

From: Ware, Michael <Ware.Michael@epa.gov>
Sent: Monday, December 6, 2021 9:20 AM
To: Allen, Joel <Allen.Joel@epa.gov>; Detmer, Sharon <Detmer.Sharon@epa.gov>; Graff, Jaimie <Graff.Jaimie@epa.gov>; Hoopes, Maria <Hoopes.Maria@epa.gov>; Lazorchak, Jim <Lazorchak.Jim@epa.gov>; Linda Platt (ucoumom@cinci.rr.com) <ucoumom@cinci.rr.com>; Oshima, Kevin <Oshima.Kevin@epa.gov>; Pat Papoi <ppapoi@fuse.net>; 'Tetens-Woodring, Joanne (tetensje)' <tetensje@ucmail.uc.edu>; Thoeny, William

<Thoeny.William@epa.gov>; Venkatapathy, Raghuraman <Venkatapathy.Raghuraman@epa.gov>; Villegas, Eric <Villegas.Eric@epa.gov>; Ware, Michael <Ware.Michael@epa.gov>; Weaver, Paul <Weaver.Paul@epa.gov>
Subject: EPA animal testing targets

See below--- I would not be shocked if the target dates return at some point

EPA Strips Wheeler's Animal-Testing Targets From Revised NAM Work Plan

December 3, 2021

EPA has published a revised version of its work plan for new alternate methods (NAMs) of chemical toxicity testing that removes all references to former Administrator Andrew Wheeler's directive to generally eliminate animal testing from the agency's work by 2035, signaling its potential retreat from what environmentalists said was an unrealistic goal.

With no public announcement, EPA posted to its website Dec. 2 an updated "New Approach Methods Work Plan," that duplicates some elements of the Trump-era original, including its title and cover, but makes no mention of Wheeler's goals for reducing agency requests for and funding of mammalian animal testing 30 percent by 2025 and eliminating them by 2035.

For instance, while the June 2020 work plan opens with a summary of Wheeler's September 2019 directive, the update cuts that language entirely and replaces it with a general statement of support for a shift away from animal tests and toward NAMs.

"Reducing the use of vertebrate animals for toxicity testing is a priority for [EPA] and, as such, the Agency is working on the development and application of [NAMs]. NAMs are defined as any technology, methodology, approach, or combination that can provide information on chemical hazard and risk assessment to avoid the use of animal testing," it reads.

The updated document no longer contains any references to 2025 and 2035 as targets for that transition. Instead, the document lays out a series of steps that the agency intends to take to advance the use of NAMs and reduce animal testing that run through 2024 -- and no further.

Where the original document describes "the short- and long-term strategies it will deploy . . . and the different deliverables on which the Agency will focus, so the public can track EPA's progress towards meeting the 2025 and 2035 goals," the new document says it "discusses the near- and long-term strategies it will deploy through 2024 . . . and the different deliverables on which the Agency will focus, so the public can track EPA's progress."

The agency's website for the work plan, updated Dec. 2, notes only that "EPA's [NAMs] Work Plan was created to prioritize agency efforts and resources toward activities that aim to reduce the use of vertebrate animal testing while continuing to protect human health and the environment. The original EPA NAMs Work Plan was released in June 2020 and laid out the Agency's objectives and strategies. The updated EPA Work Plan was released in December 2021."

EPA did not respond to a request for comment on the directive's status -- which has been in limbo since the end of the Trump administration -- by press time.

However, Biden administration officials had previously told EPA's research advisors that the Wheeler policy was being reconsidered, raising expectations that it would be revised or dropped even before the new work plan's arrival.

Advocates' Praise

Despite the apparent cut of Wheeler's strict deadlines, animal-welfare groups that support NAMs and welcomed Wheeler's policy are nonetheless welcoming the revised plan, especially for its expansion of language that originally aimed to reduce testing on live mammals to instead include all vertebrate animals.

That change aligns with language Congress added to the Toxic Substances Control Act (TSCA) in its 2016 overhaul of the law, directing EPA to "reduce and replace, to the extent practicable, scientifically justified and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances."

In a Dec. 3 statement, the Physicians Committee for Responsible Medicine (PCRM) notes EPA's updated work plan "increases the EPA's efforts to reduce and replace testing on all vertebrates by expanding the first work plan's focus beyond mammals, to include fish, amphibians, and birds. This is a huge step in protecting all animals from chemical tests and unsafe chemicals."

"We are pleased to see that the plan confirms that the reduction and replacement of animal tests is a priority for the agency, since it is certainly a priority for the American people," Kristie Sullivan, PCRM's vice president of research policy said in the statement.

And Amy Clippinger, vice president of regulatory testing at People for the Ethical Treatment of Animals, lauded the update in a Dec. 3 statement for its descriptions of "concrete steps that the agency will take in the coming three years to reduce tests on animals for pesticides and industrial chemicals. . . . The EPA Work Plan also highlights that non-animal methods have the potential to increase the 'rigor and sophistication' of chemical assessment by the agency."

NAMs Not 'Ready For Prime Time'

As early as the first weeks of the Biden administration, top EPA officials were already voicing doubts on the Wheeler directive, including Chris Frey -- who has since been nominated as the head of the Office of Research and Development (ORD), and won a majority vote from the Senate Environment and Public Works Committee on Dec. 1 to clear his path to a confirmation vote on the Senate floor.

Frey was one of several research office officials who told a Feb. 2 meeting of the agency's Board of Scientific Counselors (BOSC) that the ambitious directive would be reconsidered, though he noted at the time that any final decision would wait for the then-pending confirmation of Michael Regan as EPA administrator.

Frey, a former EPA science advisor who was then serving as ORD's deputy assistant administrator, was among the leading critics of Wheeler's 2019 testing directive prior to the 2021 transition. As a private citizen, he called the policy an effort "to kneecap science" by forcing the agency to move away from traditional animal testing before NAMs had been validated as replacements, creating a risk that the novel methods would miss health risks animal tests would catch.

He echoed that line of thought in the BOSC meeting, telling one member who asked about the transition, "I share the premise of your question and appreciate why you're asking. . . . We need to consider when is the science ready for prime time on NAMs and what is the schedule."
But he also told BOSC members that he did not want to "get in front of" Regan.
The new work plan, like the 2020 original, concludes with a list of "milestones/deliverables," which are largely similar, but which have also been mostly pushed back from the original proposed timelines. The milestones are grouped to match the five objectives of the work plan, which remain unchanged from the Trump-era document.
These include evaluating the existing regulatory flexibility for EPA's use of NAMs; developing "baselines and metrics for assessing progress"; establishing confidence in NAMs and demonstrating their "application to regulatory decisions"; developing NAMs that can "address scientific challenges and fill important information gaps" and engaging with stakeholders.
For example, where the original plan said National Academy of Sciences (NAS) would issue a report reviewing "the uncertainties and utility of existing information from mammalian toxicity tests in the context of NAM development" in the last quarter of 2022, the updated plan says NAS' study "is funded by the EPA, but the timing is determined by" NAS and estimates a 2023 release date. The NAS committee will hold its first public workshop Dec. 9.
Similarly, where the original plan said EPA would issue a report on its "review of existing statutes, programmatic regulations, policies, and guidance that relate to mammalian testing and the implementation and use of appropriate NAMs for regulatory purposes," in 2021, the update says that the report on statutes and guidance on "vertebrate animal testing" is due in 2022. -- *Maria Hegstad* (mhegstad@iwpnews.com)

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