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Short on Specifics, Long on Time Frame, 'Cures' USDA/OLAW Report Draws Mixed Reactions

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A much-anticipated final report required by the 21st Century Cures Act on ways the government can reduce administrative burdens on research involving animals is evoking mixed responses from stakeholders, with some hopes for real change already dampened by the draft version. But at least one group representing institutions contends that the multiyear effort to produce the report falls short of complying with Congress' mandate specified in the act.

The Cures Act required HHS, through the Office of Laboratory Animal Welfare (OLAW) and the U.S. Department of Agriculture (USDA), principally involving its Animal and Plant Health Inspection Service, to "complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals." The Food and Drug Administration (FDA) was also involved.

The deadline for the review was December 2018, two years from enactment of the act. The agencies technically met the deadline by issuing a draft report Dec. 7.

The final report was published Aug. 28 to little fanfare. NIH posted a grants guide notice announcing the release but offering no details as to its contents. In contrast, when the draft was issued, Mike Lauer, deputy director of NIH's Office of Extramural Research, discussed it on his blog.

The report contains agencies' responses to recommendations from a working group composed of USDA, OLAW and FDA representatives. In crafting the report, the working group held a "listening session" in January 2018 to hear directly from a variety of stakeholders ("As Agencies Review Regs, Animal Groups Urge Alternatives, Inclusion," *RRC* 15, no. 2).