

Why GAO Did This Study

U.S. research facilities use a wide range of animal species in research, and some procedures used during such research cause animals pain or distress. Federal laws and principles require that researchers consider alternatives to animal use, such as *in vitro* methods and computer modeling. HHS, USDA, and EPA conduct and fund animal research and regulate products tested on animals. HHS and USDA also oversee federal and nonfederal research facilities including researchers' consideration of alternatives to animal use.

GAO was asked to review issues related to alternatives to animal research. This report (1) describes how HHS, USDA, and EPA ensure researchers consider the use of alternatives to animals and (2) examines the steps the agencies have taken to facilitate the use of alternative research methods and to assess the effect of their efforts on animal use. GAO reviewed documents, such as agency policies and practices relevant to the consideration of alternatives and interviewed agency officials. GAO also interviewed representatives of a nongeneralizable sample of 12 federal and nonfederal research facilities randomly selected across agencies and facilities.

What GAO Recommends

GAO recommends that HHS's National Institute of Environmental Health Sciences facilitate the establishment of an interagency workgroup to develop metrics for assessing progress on the development and promotion of alternatives to animal use and incorporate those metrics into public reports. HHS agreed with our recommendation.

View [GAO-19-629](#). For more information, contact Steve Morris at 202-512-3841 or morriss@gao.gov

ANIMAL USE IN RESEARCH

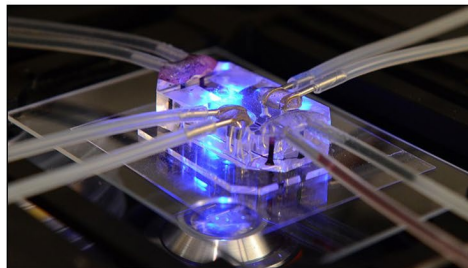
Federal Agencies Should Assess and Report on Their Efforts to Develop and Promote Alternatives

What GAO Found

The Department of Health and Human Services (HHS), U.S. Department of Agriculture (USDA), and Environmental Protection Agency (EPA) use a variety of methods to ensure researchers consider alternatives to animal use in research (see figure). Two of these methods are (1) requiring researchers to obtain approval of their research protocols, including their consideration of alternatives, from their institutions, and (2) calling for or recommending researchers to use database searches to identify alternatives. HHS and USDA also help ensure that researchers consider alternatives through the agencies' oversight of research facilities. For example, USDA is to conduct annual inspections of nonfederal research facilities. Furthermore, the agencies have provided training to researchers on the consideration of alternatives.

HHS, USDA, and EPA have facilitated the development and use of alternatives to animal use in research through individual and collaborative efforts. These efforts include agency strategies and policies for promoting the use of alternative methods and the development of testing methods that rely on non-animal models. Additionally, the agencies are members of the Interagency Coordinating Committee on the Validation of Alternative Methods, which is managed by HHS's National Institute of Environmental Health Sciences. The committee promotes testing methods that protect human health and the environment while reducing animal use. The interagency committee's 2018 strategic roadmap calls for it to identify appropriate metrics for monitoring progress and measuring success in adopting alternatives. However, the committee and its member agencies have not routinely developed or reported metrics that demonstrate how their efforts to encourage the use of alternative methods affect animal use. They have also not designated an interagency workgroup to address the challenges related to developing and reporting such metrics. Facilitating the establishment of such a workgroup would help the committee and its member agencies better monitor their progress across the range of their efforts to reduce animal use and report members' progress to the public.

Examples of Methods to Replace, Reduce, or Refine Animal Use in Research



Alternatives that replace, reduce, or refine animal use include tissue chips (left) that are lined with living cells and contain features designed to replicate the complex biological functions of specific organs, and zebrafish (right), which are inexpensive to house, reproduce quickly, and have transparent embryos in which biological functions are easily observed.

Sources: Wyss Institute for Biologically Inspired Engineering, Harvard University (left photo); <https://www.goodfreephotos.com> (right photo). | GAO-19-629