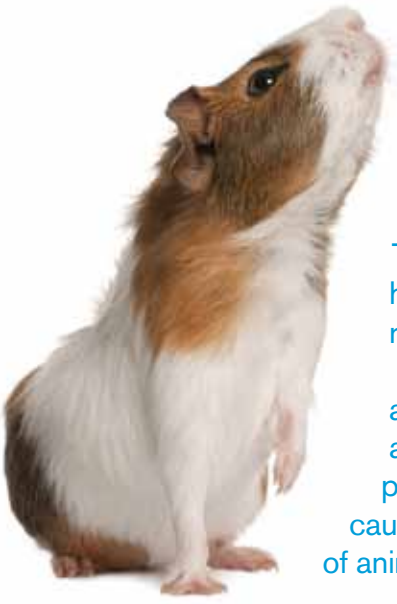
Reducing EPA's Animal Testing

By Catherine Willett, Patricia Bishop, and Kristie Sullivan



In the 1990s, environmentalists sounded alarms that chemicals, particularly those in pesticides that seek to disrupt the reproductive cycle of 'pest' insects, may be causing damaging effects on the endocrine systems of humans and wildlife. The endocrine system coordinates the body's hormonal activities, including those affecting reproduction and metabolism.

This article is based on information the authors presented at the 8th World Congress and critically examines the U.S. government's plans for a massive testing program that will cause the suffering and death of literally millions of animals, unless alternatives are put in place.

The potential health effects of environmental exposure to chemicals with endocrine activity have been a topic of much concern in the media in recent years. Proving a causal relationship between exposure and effects at either the individual or population level is exceedingly difficult. Nonetheless, Congress instructed the Environmental Protection Agency (EPA) to test chemicals for endocrine activity, and the agency focused on the possible effects of the reproductive and thyroid systems in humans and wildlife. More than 10 years later, EPA launched its Endocrine Disruptor Screening Program (EDSP) in 2009.[1]

The current EDSP design is organized into two stages, or 'tiers,' of tests. Tier 1 consists of six animal (*in vivo*) tests and five non-animal (*in vitro*) tests that are intended to screen chemicals for the *potential* to interact with the endocrine system.[2] Tier 2 has not been finalized, but is likely to consist of developmental and reproductive toxicity tests using several animal species to observe potential adverse effects that might result from the activity identified in Tier 1. Conducting all eleven EDSP Tier 1 tests would require a minimum of 520 animals and cost between $335,100-$964,250 *per chemical*.[3,4] It is not yet possible to estimate the cost of Tier 2 testing; however, the typical reproductive toxicity test in mice or rats kills 2,600 animals and costs about half a million dollars.

GETTING STARTED

The first chemicals to be tested in the EDSP include 58 pesticide active ingredients and nine common chemicals used as pesticide ingredients. If all of the Tier 1 tests were performed for all 67 chemicals, more than 35,000 animals would be consumed and testing would cost more than 36 million dollars. (See page 23) Yet, this is only the screening phase, designed to identify substances that have the potential to interact with the reproductive or thyroid hormonal systems. In the short-term, EPA plans to evaluate all pesticides and chemicals found in potential sources of drinking water, somewhere between 6,000-10,000 chemicals. Eventually, EPA and other regulatory programs would like to test all marketed chemicals; estimates of this number vary from 30,000-80,000. Clearly, considering the high cost of the Tier 1 testing, in terms of money and animal lives, this approach should be reconsidered.

A DIFFERENT APPROACH

The efficiency of screening and testing chemicals for endocrine activity can be significantly improved by taking a more integrated approach based on the properties of the chemical.[5] Starting with a full evaluation of existing data, including physical and chemical properties, information about biological activity and known exposures, chemicals of greatest concern can be prioritized for further evaluation.

Of course, some might argue that cost, especially in dollar terms, and perhaps even in terms of animals killed, is of minor consideration if it effectively protects humans and the environment from harmful chemicals. However, the fact is that data obtained from animal testing is of questionable protective value: the results are highly variable, difficult to repeat, and hard to use for making decisions about chemical safety.[6] Better approaches are being developed that not only save animals, but provide information that would be much more useful in achieving human environmental safety.

Several evaluation methods that do not involve animal testing currently exist that can be used to gain more information about a chemical. For example, there are a number of computer models that can predict a chemical's biological activity based on its structure, and EPA is developing a large array of *in vitro* tests that can be used to prioritize chemicals according to potential endocrine activity.[7] Only after these assessments are

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performed would any animal testing be considered, which would greatly reduce the number of animals used in evaluating the endocrine effect of chemicals. Using the pesticide atrazine as an example, we showed that 77 percent of the animals killed in the EDSP Tier 1 assays could have been saved if such an integrated approach had been followed.[8]

FUTURE DIRECTION

EPA has begun the process of revising its approach to the screening of chemicals for potential endocrine activity. As a result of instructions from the Office of Management and Budget (OMB),[9] the U.S. House of Representatives Appropriations Committee for the Interior and Environment,[10] and the EPA's own Office of the Inspector General,[11]—all of which directed the agency to improve its methods of evaluation—EPA has issued a work plan for incorporating *in vitro* assessment tools into the EDSP.[12] This will help EPA prioritize the list of chemicals to evaluate, with the eventual goal being the replacement of the current Tier 1 testing with a completely *in vitro* screening approach. EPA has also issued a document describing how it will evaluate all available information in a more comprehensive way,[13] and while this document is somewhat vague in the details, it heads in the direction of a more thoughtful evaluation. Although falling short of a true integrated strategy as outlined here, EPA's new plan for the EDSP does describe a more efficient approach than it is currently taking and, as a result, is likely to lead to decreased reliance on animal testing.

OUR ROLE

As a final note, much of the progress described here was influenced by animal protection groups. We met with the Office of Management and Budget, which provides oversight of federal agencies, and with members of Congress to argue the high cost versus low benefit of the program. We also submitted numerous comments to and met with EPA to discuss problems with and solutions to the existing EDSP organization, and made several public presentations discussing potential solutions. And as the program continues, we will continue with our partners to push for progressive improvements to reduce the use of animals. **AV**

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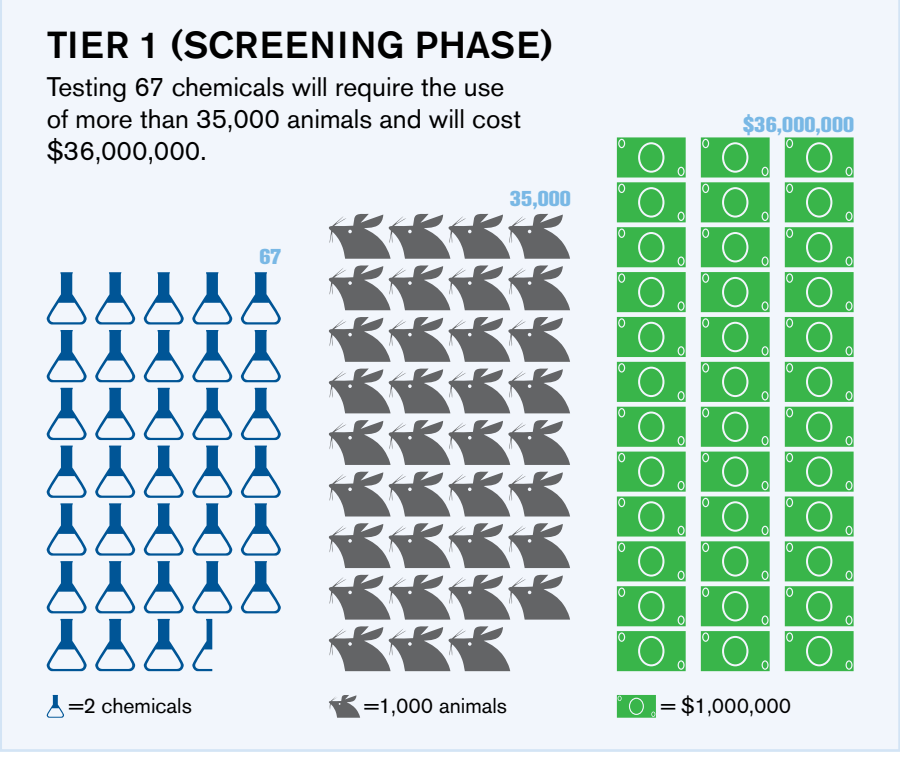

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