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RATS, RABBITS, AND THE EPA

Most readers are well aware that nonhuman animals are used in a variety of biomedical research programs. Courses in environmental ethics often devote some attention to such research because its moral justifiability clearly depends, at least in part, on the moral status of the animal subjects. What is not as widely known, however, is that very many of the animals used as research subjects are used not to find a cure for cancer or an AIDS vaccine but rather to satisfy the regulatory requirements of the U.S. Environmental Protection Agency (EPA). We excerpt a small section of such a research protocol here:

> 4.3.3.1 Repeated-Dose Toxicity Test Methodology
>
> Repeated-dose toxicity studies evaluate the systemic effects of repeated exposure to a chemical over a significant period of the life span of an animal (rats, rabbits, or mice). Chronic repeated-dose toxicity studies are concerned with potential adverse effects upon exposure of the greater part of an organism's life span (e.g., one to two years in rodents). Subchronic repeated-dose studies are concerned with the effects caused by exposure for an extended period, but not one that constitutes a significant portion of the expected life span. Subchronic studies are useful in identifying target organ(s), and they can be used is selecting dose levels for longer-term studies. Typically, the exposure regimen in a subchronic study involves daily exposure (at least 5 consecutive days per week) for a period of at least 28 days or up to 90 days (i.e.,

about 4 to 13 weeks). A recovery period of two to four weeks (generally included in most study designs) following completion of the dosing or exposure period provides information on whether or not the effects seen during the exposure period are reversible upon cessation of treatment. The dose levels evaluated in repeated-dose toxicity studies are notably lower than the relatively high limit doses used in acute toxicity studies. The NOAEL (no observed adverse effect level), usually expressed in mg/kg/day, defines the dose of test material that produces no significant toxicological effects. If the test material produces toxicity at the lowest dose tested (i.e., there is no defined NOAEL), the lowest dose that produced an adverse effect is defined as the LOAEL (lowest observed adverse effect level). While these studies are designed to assess systemic toxicity, the study protocol can be modified to incorporate evaluation of potential adverse reproductive and/or developmental effects.[1]

DISCUSSION

It is important to both human and nonhuman members of ecosystems that materials released into those ecosystems by human activity do not cause adverse effects. Hence, in setting use and exposure and discharge standards for such materials, the EPA requires and uses the results of repeated-dose toxicity tests, among other kinds of data. Whatever the long-term benefits of such standards, they certainly do not benefit the animal subjects of the tests: The animals are euthanized in the course of the research.

Consider a single material. Zinc dialkyldithiophosphate is a chemical that can be added, in very small amounts, to lubricating oils. In engine oil, along with other additives, it prolongs the oil's useful life (thereby reducing the volume of new oil needed and the volume of dirty oil to be disposed of) and improves its performance (thereby increasing vehicle mileage, thus reducing gasoline consumption). It is also relatively persistent: When zinc dialkyldithiophosphate finds its way into the soil or into surface or groundwater systems, it remains there for a long time. This raises a number of important regulatory issues: Should the EPA permit petroleum companies to use the material as an oil additive? Will organisms subjected to repeated-dose exposure to the material be adversely affected? In part, an ecologically responsible answer to the first question would seem to require a scientifically robust answer to the second.

QUESTIONS

1. Much of the animal experimentation performed for medical purposes is designed and intended solely to benefit human beings. But the repeated-dose toxicity evaluation of zinc dialkyldithiophosphate is intended to protect not only humans (such as automobile mechanics) but also the ecosystems into which the material may be released. Does the fact that other animals and even whole ecosystems may benefit from such research change any of the moral issues posed by the (lethal) use of animals in the research studies? If so, how?
2. Is it easier or more difficult to justify the use of rabbits in repeated-dose toxicity studies of zinc dialkyldithiophosphate than it is to justify their use in equally lethal tests of, for example, a potential asthma medication or a new ingredient for a cosmetic?
3. In general, the larger the number of animals used in a particular test, the more reliable the results of the study. For example, we can better evaluate the carcinogenic potential of a substance if it is tested on 1,000 rats than if it is tested on 100. How should the EPA strike a balance between the value of better data and the number of test animals used to obtain it?
4. The rats used in experiments such as the one described in this case are bred specifically for such testing. They would not exist if they had not been bred specifically for use as test animals. Is this fact relevant to the question of whether using the animals as research subjects is moral?

NOTE

1. American Chemical Council, Petroleum Additives Panel, Health, Environmental, and Regulatory Task Group, "High Production Volume (HPV) Challenge Program: Test Plan for Zinc Dialkyldithiophosphate Category," September 24, 2002, available at www.epa.gov/chemrtk/zincdial/c14066tp.pdf. Recent testing protocols for a wide range of chemicals are available from the EPA at www.epa.gov/chemrtk/whatsnew.htm.

SOURCE

American Chemical Council, Petroleum Additives Panel, Health, Environmental, and Regulatory Task Group. "High Production Volume (HPV) Challenge Program: Test Plan for Zinc Dialkyldithiophosphate Category." September 24, 2002. Available at www.epa.gov/chemrtk/zincdial/c14066tp.pdf.