

## USDA Suspends License for Engineered Vaccine

The U.S. Department of Agriculture (USDA) has temporarily suspended a company's license to market an animal vaccine made by recombinant DNA methods. The suspension follows charges by activist Jeremy Rifkin that the department did not properly review data on the vaccine, which is made from a live virus, before the license was originally approved. His assertions have prompted two House subcommittees to schedule a joint hearing for 29 April to discuss the matter.

The vaccine, a virus with one gene deleted, became the first virus modified by recombinant DNA techniques to be released into the environment when it was approved by USDA in January. It protects against pseudorabies, a widespread disease among livestock, especially swine.

Rifkin petitioned USDA on 3 April to revoke the license to market the vaccine. He charged that the department did not follow the correct procedures for reviewing a genetically engineered product and that it did not conduct a proper assessment of the potential consequences of releasing the virus into the environment (*Science*, 18 April, p. 316). Shortly afterwards, the department suspended the license and halted sale of the vaccine for 2 weeks, from 9 to 22 April.

But Bert W. Hawkins, administrator of the regulatory branch of USDA, denied that the safety review was faulty and asserted that USDA's analysis was scientifically sound. Hawkins said that the department will use the suspension period to "document our procedures more fully with respect to the environmental assessment of the vaccine's use" to assure the public that no environmental hazards exist. The suspension "in no way suggests any lack of confidence by USDA in the safety and efficacy of this product or in the adequacy of the measures we have taken . . .," Hawkins said in a letter to Rifkin.

Rifkin has asserted that the license application should have been evaluated by the department's biotechnology committee, but Hawkins said in an interview that data on the vaccine would not be submitted to the committee. He said that USDA officials initially determined that the application was exempt from the panel's review because the vaccine's safety was established by company test data and experience with similar live pseudorabies vaccines already on the market. An in-depth evaluation by the committee at this point "would be expensive [and] time con-

suming, and [is] not required," he asserted.

Thomas Bevard, an official at Biologics Inc. of Omaha, Nebraska, which produces the vaccine, said a 2-week suspension will not significantly hurt sales, but any further delay could be damaging. Bevard said that the additional review by USDA "isn't necessary, but if that is what it takes to clear up questions about the vaccine, let's do it." Bevard added that Rifkin's charges and the ensuing publicity "caught us totally by surprise."

Although press reports have said that USDA had quietly approved the license application, Bevard noted that the vaccine had been widely discussed among veterinarians and livestock growers for some time. And after the vaccine was approved, "we sent out all kinds of publicity, but no one paid any attention."

Rifkin's attack on USDA's review process comes at a time when federal agencies are in the final stages of formulating a policy on how to regulate biotechnology. A broad proposal was circulated a year and a half ago and is expected to be released in its final form in about a month. ■ MARJORIE SUN

## Laser Fusion Program Burdened by Overclassification

The National Academy of Sciences' forthcoming assessment of inertial confinement fusion (ICF) research is expected to call for declassifying many aspects of the program. The ICF review committee concludes that the present classification system is obstructing the flow of information among scientists and slowing development of the technology. The long-awaited report—which is itself classified and has not yet been published in an unrestricted form—recommends keeping under wraps only those portions of the program directly related to weapons design, say government and university officials who have had access to the report.

The report faults the Reagan Administration's plan to fund inertial fusion work through the Department of Energy's (DOE) research, development, testing, and evaluation program budget, and recommends maintaining the program as a distinct entity within DOE. Supporters of the fusion program have feared that generic energy production aspects of ICF research would suffer if the program is loosely mixed with DOE weapons activities that could overshadow it.

The Academy's National Research Council, which performed the review under a contract

from the Office of Science and Technology Policy (*Science*, 6 September, 1985, p. 950), first made its position known to the Administration in a 15 July letter to George A. Keyworth, then science advisor to President Reagan. William Happer, the committee chairman and a professor of physics at Princeton University, noted then that "there are serious problems with including the ICF program in the RDT&E portion of the DOE weapons program."

An edited version of this classified interim report was not made public until 17 March, however. The summary was released in response to a freedom-of-information request filed by Stephen O. Dean, president of Fusion Power Associates, the industry trade organization. Since Happer reported to OSTP in July, the review committee has conducted more research, but, the key findings enunciated by Happer 9 months ago are fundamentally the same, according to knowledgeable government and university officials.

While the laser technology is likely to be used first to create controlled, miniature thermonuclear reactions for modeling nuclear weapons, DOE also has supported the program because of the technology's potential application in a fusion reactor to produce electricity. In recent years, however, the Administration has sought to phase down the research program and to concentrate on military applications. Congress in 1986 rebuffed White House efforts to cut this research, and provided \$155 million in funding. Unable to ignore deficit reduction pressures, the House Armed Services Committee may allow DOE support to drop to \$23.8 million in 1987. But it still is expected to insist that a separate line item for the program be maintained.

In his July report, Happer said the line-item budget provision is needed to sustain research efforts at smaller research establishments such as the Naval Research Laboratory and the University of Rochester. Although the largest research lasers are located at Livermore, Sandia, and Los Alamos national laboratories, Happer notes that the research conducted by smaller institutions may be critical to designing laser drivers hot enough to produce a thermonuclear burn.

Although the ICF committee finds that significant headway has been achieved toward a sustained burn of a laboratory pellet, Happer says a decision whether to proceed with the research could be delayed without "steady, rational funding of the program over the next few years." In testimony before the House Armed Services Committee in February, Happer indicated that if current research efforts are completed, program administrators will have adequate data to decide whether to proceed with further research. In the judgment of the review committee, expensive up-