

primarily cattle, and that swine react differently to FMD in general, we do not consider swine to be critical as the primary focus of serological surveillance.

One commenter asked whether the results of the sampling of sheep that was scheduled to be completed by May 2002 were available. A serological survey of the sheep population of Uruguay was conducted between May and August 2002. The survey was designed to detect virus activity in 1 percent of the sheep population and to identify sheep flocks with 5 percent or more infected sheep. Three groups were defined for sampling by geographical strata based on distance from the nearest FMD focus in previous outbreaks: Stratum I—less than 5 km, stratum II—5–10 km, and stratum III—greater than 10 km. Within each group, sheep operations were randomly selected in proportion to flock size.

The survey sampled 18,296 sheep from 340 flocks. Using the Virus Infection Associated Antigen (VIAA) test, the estimated seroprevalence for antibodies to the FMD virus was 0.16 percent. The results show a decline from a previous survey. By geographic area, the seroprevalence was 0.23 percent in stratum I, 0.08 percent in stratum II, and 0.04 percent in stratum III. A subsequent epidemiological investigation of the 20 seropositive animals concluded that the positive results were due to residual antibodies from exposure during the previous epidemic.

Because unvaccinated sheep were not involved in large numbers during the most recent outbreak of FMD, one commenter questioned the utility of using unvaccinated sheep as sentinels for the virus. We agree that sheep were not a major factor in the establishment and spread of FMD during the 2001 outbreak in Uruguay. In addition, the available evidence suggests that sheep may not be good sentinels for detecting the presence of clinical disease. However, the serological evidence provided by Uruguay indicates that sheep may serve as serological sentinels based on the data on seroconversion that were received during surveys conducted in 2001. Monitoring the fluctuations in the levels of antibodies that the sheep develop will give scientists and veterinarians a warning about the presence of FMD.

One commenter asked if serosampling since February 2002 has continued to show a decline in prevalence. Serological sampling of the cattle population in November 2002 indicated a decline in FMD prevalence compared to previous surveys. As stated in the risk assessment, Uruguay conducted two serological surveys in 2001 and 2002 in the cattle population, using the 3ABC enzyme-linked immunosorbent assay (ELISA) to detect antibodies against FMD non-structural protein. The seroprevalence of FMD was estimated to be 9.26 percent in 2001 and 2.3 percent in February 2002.

Using the 3B ELISA test for non-structural antibodies to the FMD virus, the estimated seroprevalence in November 2002 was 1.98 percent. Sera positive on the 3B ELISA were retested using the 3A ELISA in order to increase specificity, resulting in an adjusted seroprevalence estimate of 0.65 percent. This indicates that there is a declining trend of non-structural antibodies.

One commenter asked whether the USDA had looked at the test kit variation for the 3ABC ELISA test. We have evaluated test results obtained by Uruguay in their serological survey conducted in February 2002 in cattle. The data were obtained using two different 3ABC ELISA kits (United Biomedical Incorporated (UBI) and Pirbright 3ABC ELISA kits) and the Virus Infection Associated Antigen (VIAA) test. The types of tests and the results obtained during that survey are provided in table 2. The FMD prevalence estimates provided by Uruguay were based on results obtained using the UBI kit. After retesting of serum samples using the Pirbright 3ABC ELISA kit and the VIAA test, the data showed a three-fold reduction in the number of positive samples. However, the number of positive samples in the two additional tests were quite comparable. In order to maximize the risk estimates, APHIS used the prevalence estimates that were obtained using the UBI kit in the quantitative risk assessment.

TABLE 2.—SEROLOGICAL SAMPLING IN CATTLE IN URUGUAY 2002

Regions*	Holdings sampled	Holdings with positive sera—		
		UBI	Pirbright 3ABC	VIAA
Stratum I (< 5 km)	59	18	7	10
Stratum II (5–10 km)	65	16	6	5
Stratum III (>10 km)	75	15	5	2

* Regions for sampling were established based on their distance from the nearest FMD focus in the previous outbreaks.

One commenter noted that the site visit report states that “[a]lthough the team felt that positive 3ABC ELISA tests may not be a result of field virus, that possibility cannot be totally excluded,” and asked if more serological surveys will be done to exclude the possibility of circulating FMD virus.

We will continue to monitor the situation in Uruguay and will evaluate the results of serological surveys being conducted by Uruguay. We evaluated data from the two previous serological surveys conducted in 2001 and 2002 and concluded that serological surveillance and sampling schemes were adequate. In addition, APHIS

concluded that the official national laboratory in Montevideo, which is the only laboratory approved to carry out FMD serological testing in Uruguay, has the capacity to run valid serological tests for FMD.

Based on the serological data provided by Uruguay, APHIS could not exclude the possibility that positive 3ABC ELISA tests are due to field virus. APHIS believes that this possibility cannot be excluded under any circumstances. In the July 2002 site visit report, APHIS mentioned that the positive results were likely due to the use of partially purified or unpurified vaccines, or to false-positive tests for the

following reasons: (1) There was a declining pattern of FMD prevalence in the two surveys, which indicates that the positive response may not be due to infection; (2) the distribution of the positive holdings was quite comparable among the three different geographical regions (strata I, II, and III), which suggested false-positive tests since both strata II and III did not include any farms with registered FMD cases at any time during the outbreaks; and (3) when the sera were further processed by the central laboratory using 3ABC ELISA kits from a different source, in addition to the VIAA test, the number of positives was markedly reduced (see