

Technical Bulletin 1

Neospora Caninum Vaccine Field Safety Evaluation

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Summary Points

- Seven hundred fifty-seven cows from seven farms were used in the study.
- The herds used had no previous history of reproductive problems.
- Vaccinates received two injections of *Neospora caninum* vaccine 21 to 28 days apart.
- Controls received two injections of saline at the same interval.
- Cattle were pregnancy tested by palpation 60 to 90 days following the second vaccination.
- The *Neospora caninum* vaccine is safe for use in healthy, pregnant dairy cattle.
- Injection site reactions were insignificant or similar to those seen with other vaccines.

Neospora Caninum Vaccine Field Safety Evaluation

I. Summary

A field study evaluation of 757 cattle from seven farms in California, Missouri and New York was conducted to determine the safety of, and assess injection site reaction to an experimental *Neospora caninum* vaccine. The healthy, pregnant cattle used in the study received two doses of the test vaccine, 21-28 days apart, while the control cattle received two injections of saline at the same interval. The cattle were pregnancy tested by palpation 60 to 90 days following the second vaccination.

The study determined that the experimental *Neospora caninum* vaccine is safe for use in healthy, pregnant, dairy cattle. Vaccinates delivered healthy, normal calves more frequently than did the control group. Although the data was not statistically significant, there were more open cows in the control group than among the vaccinates. Analysis of the injection site data concluded that site reactions were insignificant or similar to those seen with other vaccines. In New York, no cows exhibited injection site swellings; in California, two cows exhibited small nodules, and in Missouri, minimal injection site swellings were observed.

II. Introduction

Neosporosis, caused by the coccidian parasite *Neospora caninum*(1), is a major cause of abortion in cattle(2). Though abortion is the only clinical symptom exhibited by infected animals, the disease generates significant economic losses due to lost fetuses, costs associated with rebreeding, decreased lactation time, loss of milk yield and replacement of culls. Cases have been reported worldwide with an estimated 40,000 *Neospora*-induced abortions occurring in California annually(3).

Until identification of the organism in 1988, *Neospora caninum* infections had been attributed to *Toxoplasma gondii* due to biological and structural similarities between the causative organisms. Although dogs are the definitive host of this parasite(4), it frequently infects sheep, goats, deer, horses and, most importantly, cattle as intermediate hosts.

III. Materials and Methods

A total of 757 cows from commercial dairy herds without a history of reproductive problems in California, Missouri, and New York were included in the study. The cows, which were confirmed to be pregnant by palpation in either the first or second trimester, were randomly divided into vaccinate and control groups. The vaccinate groups were further divided into subgroups to compare two serials of the experimental *Neospora caninum* vaccine to be evaluated at each location. Vaccinates were not, however, cross-vaccinated with both serials.

Table 1. Enrollment of cows in the study.

Location	1st Trimester			2nd Trimester			Totals
	Control	Serial 1	Serial 2	Control	Serial 1	Serial 2	
*NY	60	30	30	60	30	30	240
*MO	24	12	12	27	13	13	101
MO	3	2	2	13	7	7	34
MO	4	2	2	7	4	3	22
MO	7	1	2	3	4	3	20
MO	25	13	12	25	13	12	100
*CA	60	30	30	60	30	30	240
Totals	183	90	90	195	101	98	757

*NY = New York, MO = Missouri, CA = California

The initial injection was given subcutaneously, using aseptic technique, on the left side of the neck. The booster was given on the right side of the neck 21 to 28 days following the initial injection. Cows were observed for adverse reactions by the attending veterinarian for two hours following injection and were assessed for injection site reactions 3, 7, and 10 or 14 days following each dose of the vaccine. Herd owners reported any abnormal reactions, observed cows between scheduled veterinarian visits, and conducted a final pregnancy exam 60 to 90 days following administration of the final dose of vaccine. In addition to the above safety parameters required by the USDA, the number of normal calves delivered to both the control and vaccinate groups was recorded.

IV. Results

Pregnancy results from the trial are summarized in Table 2⁹. Of the initial 757 cows, 714 remained in the trial until the final pregnancy examination. The other 43 cows were sold prior to the end of the trial due to lameness, mastitis, injury or other illness.

Table 2. Pregnancy results.

	Trial Beginning	Trial End	Number Pregnant	Number Open	Delivered Normal Calves
Vaccinates	379	355	340	15	319
Controls	378	359	341	18	315

Injection site reactions varied among herds and by state. Veterinarians attending the larger herds (New York and California) reported no injection site reactions or a limited number of reactions <1.5 cm occurring with either the initial or booster vaccinations. The Missouri herds displayed a wider variation of injection site reactions. Most of the reactions observed in Missouri were under 2.5 cm. Larger reactions tended to resolve within 10 to 14 days.

V. Discussion

Results from the study indicate that the experimental *Neospora caninum* vaccine is safe and does not produce unwanted injection site lesions or swelling. The number of site reactions differed among the study locations with the herds in Missouri experiencing the greatest incidence of reactions. Abnormally high environmental temperatures, poor hygienic conditions, and increased monitoring due to smaller herd size were possible factors identified by the study investigator that may have contributed to this result. However, attending veterinarians for the Missouri herds did not consider the reactions associated with the experimental *Neospora caninum* vaccine to be abnormal compared to those seen with other vaccines.

Of the cows receiving the vaccination, 15 were open at the second pregnancy check compared to 18 in the control group. Additionally, more of the cows that were given the experimental *Neospora caninum* vaccine delivered normal calves than did those receiving the saline injection. As would be expected in a field safety trial conducted in herds without a history of reproductive problems, these differences were not statistically significant.

VI. Conclusions

The results of the field safety evaluation demonstrate that the experimental *Neospora caninum* vaccine:

- is safe for use in healthy, pregnant cattle;
- does not adversely affect pregnancy rates or the percentage of normal calves delivered;
- does not cause excessive injection site reactions.

VII. References

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