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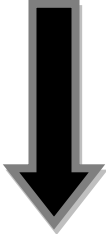
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Evaluating Vaccine Labels to Determine Expected Level of Protection

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A successful herd health program involves good management in a number of areas including proper herd immunization (vaccination) to prevent and/or control a variety of infectious diseases caused by microorganisms such as viruses and bacteria. However, selecting the proper vaccines for your herd can be a difficult task considering the large number of vaccines that are available. Therefore, some things to consider when developing a vaccination program for your herd are: 1) determine the goals of your vaccination program (e.g., what diseases do you want to prevent and/or control, and in what type/age animal); 2) discuss these goals with your veterinarian and/or extension agent; and 3) understand a vaccine's expected level of protection.

Every vaccine bottle or product insert has information related to its expected level of protection. The United States Department of Agriculture (USDA) can grant a vaccine one of five possible levels of protection based on a thorough analysis of supporting efficacy and safety data. The five levels of protection, in order from greatest protection to least protection, are:

- | | |
|-----------------------------|--|
| ▪ Prevention of infection | Highest level of protection |
| ▪ Prevention of disease |  |
| ▪ Aid in disease prevention | |
| ▪ Aid in disease control | |
| ▪ Other claims | |
| | |

The Center for Veterinary Biologics (CVB), which is part of the Animal and Plant Health Inspection Service (APHIS) of the USDA, is the agency that evaluates vaccines and recommends the appropriate label protection claims. Vaccine manufacturers may voluntarily choose a lesser label protection claim, but they cannot increase their label claims without the supporting data. Understanding label claims is therefore one way to evaluate the expected efficacy of a vaccine, but remember that these claims only apply when products are administered according to label directions. So, what do these levels of protection mean? First, here are some definitions that will help with understanding vaccine label claims:

- Disease – an abnormal condition affecting an animal caused by infection, nutritional deficiency or imbalance, toxicity, unfavorable environmental factors, etc; illness; sickness; ailment.

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- Infection – invasion and multiplication of microorganisms in the body.
- Challenge organism – the microorganism used to expose vaccinated animals in an effort to determine vaccine efficacy.

Vaccine Label Claims

1. ***Prevention of Infection*** – Prevents all colonization and/or replication of the challenge organism.

A claim that it is intended to prevent infection may be made only for products able to prevent all colonization and/or replication of the challenge organism in vaccinated and challenged animals. If such a conclusion is supported with a very high degree of confidence by convincing data, a label statement such as "for the prevention of infection with [specific microorganism]" may be used. However, this claim is rarely granted.

2. ***Prevention of Disease*** – Highly effective in preventing clinical disease.

A claim that it is intended to prevent disease may be made only for products shown to be highly effective in preventing clinical disease in vaccinated and challenged animals. If so, a label statement such as "for the prevention of disease due to [specific microorganism]" may be used.

3. ***Aid in Disease Prevention*** – Aids in preventing disease by a clinically significant amount.

A claim that it is intended to aid in disease prevention may be made for products shown to prevent disease in vaccinated and challenged animals by a clinically significant amount which may be less than that required to support a claim of disease prevention (see above). If so, a label statement such as "as an aid in the prevention of disease due to [specific microorganism]" may be used.

4. ***Aid in Disease Control*** – Aids in the reduction of disease severity, duration or onset.

A claim that it is intended to aid in disease control may be made for products which have been shown to alleviate disease severity, reduce disease duration, or delay disease onset. If so, a label statement such as "as an aid in the control of disease due to [specific microorganism]" or a similar one stating the product's particular action may be used.

5. **Other Claims** – Products with beneficial effects other than direct disease control.

Products with beneficial effects other than direct disease control, such as the control of infection through the reduction of pathogen shedding, may make such claims if the size of the effect is clinically significant as well as supported by appropriate data.

These Protection Statements are outlined by the USDA, APHIS, Veterinary Services Memorandum No. 800.202, June 14, 2002.

Following label directions will maximize product efficacy, so the next time you evaluate your herd's vaccination program remember to read vaccine labels for proper storage, dosage, route of administration, as well as the expected level of protection.