

Subject: Regulation of Agricultural Animals

Policy #26

References: AWA Section 13
9 CFR, Part 3, Subpart F

History: Clarifies existing internal policy.

Justification: The Animal Welfare Act (AWA) regulations cover farm animals that are used in activities that are regulated by the AWA.

Policy: Farm animals, such as domestic cattle, horses, sheep, swine, and goats that are used for traditional, production agricultural purposes are exempt from coverage by the AWA. Traditional production agricultural purposes includes use as food and fiber, for improvement of animal nutrition, breeding, management, or production efficiency, or for improvement of the quality of food or fiber.

Farm animals that are used to manufacture and test veterinary biological products intended for use in the diagnosis, treatment, or prevention of diseases in agricultural animals are, therefore, exempt from U.S. Department of Agriculture's (USDA) regulatory authority under the AWA. USDA considers this use to be agricultural research, thus, not a regulated activity.

Farm animals that are used to test and produce biologicals for nonagricultural or nonproduction animals are covered by Part 3, Subpart F of the regulations. We consider this to be nonagricultural research and testing that is covered by the AWA and the regulations. As such, when farm animals are used to test or manufacture vaccines, bacterins, toxoids, and other related veterinary biologicals that will be used exclusively in nonproduction animals such as dogs and cats and other pet animals, or in both nonproduction, as well as, farm animals, they are regulated and monitored for compliance with the regulations. An example of the latter may include rabies vaccine or other product that has a multi-species label recommendation.

Farm animals that are used as models for human subjects in order to test or manufacture biologicals that will ultimately be used in humans are also regulated. USDA considers this to be biomedical research which is a regulated activity.

