

羊痘活毒疫苗量產及安全、效力評估

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摘要

羊痘係羊隻的一種高度傳染性病毒性疾病，以皮膚發紅疹 (erythematous eruptions) 為主要特徵。病程初期，病變呈現丘疹 (popular)，隨後轉為膿庖疹 (pustular eruptions)，至全身性病變時，可能會有呼吸道和胃腸道黏膜出血性炎症反應發生並造成死亡。羊痘病毒，屬痘病毒科中之羊痘病毒屬 (Capripoxvirus)，只有一種血清型。在自然情況下，綿羊痘和山羊痘具有宿主特異性，彼此間具有免疫抗原相關性。病毒顆粒大小為 290 x 270 nm，病毒表面具有管狀小體構成絲狀結構之痘病毒。病毒核酸 DNA 長約 150 Kbp。2008 年 6 月於桃園縣爆發台灣第一起羊痘疫情，經撲殺 210 頭羊和羊舍消毒後疫情獲得控制。但 2010 年 4 月雲林縣再度爆發羊痘疫情，總撲殺淘汰頭數有 23,221 頭，約占台灣總飼養羊隻頭數的十分之一。本所緊急製造羊痘減毒活毒疫苗並依據 WOAHA (World Organisation for Animal Health) 陸生動物疫苗標準進行羊痘活毒疫苗安全、效力試驗、病毒迷入否定試驗及田間試驗，結果各項試驗均合格，並於 2011 年取得動物疫苗製造許可證(08728)，每年生產 12 至 15 萬劑量供台灣養羊產業防疫所需。

Development, Production, and Evaluation of Safety and Efficacy of a Live Attenuated Goat Pox Vaccine

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Abstract

Goat pox is a highly contagious viral disease, characterized by developing erythematous eruptions. At the preliminary disease stage, lesions appear as popular papules, and pustular eruptions develop afterwards. When systemic lesions develop, hemorrhagic inflammation in the mucosa tissues of the respiratory and gastrointestinal tracts may occur and result in mortality. Goat poxvirus (GPV) belongs to the genus *Capripoxvirus* within the *Poxviridae* family, and only one serotype of this virus has so far been documented. Sheep poxvirus (SPV) and GPV display related antigenicity, even though two viruses exhibit host specificity. Viral particles of GPV are in the size range of ~290 x 270 nm, and the particle surfaces are covered with short tubular filaments. The GPV genome is comprised of DNA at a size of 150 Kbp.

The first case of a goat pox outbreak in Taiwan occurred in Taoyuan County in June 2008, and the outbreak was contained after the culling of 210 sheep and the disinfection of animal facilities. However, in April 2010, another goat pox outbreak in Yunlin County ensued, and 23,221 goats (accounting for one-tenth of the total number of goats raised in Taiwan) were culled. After these events, the Animal Health Research Institute urgently developed and manufactured a live attenuated goat pox vaccine. Follow-up evaluations of safety, efficacy, reversion to virulence and field trials of the vaccine were conducted according to the terrestrial animal vaccine standards outlined by the WOA (World Organization for Animal Health). All the results of these evaluations were qualified, and the animal vaccine manufacturing license (License NO. 08728) was issued in 2011. Currently, 120,000 to 150,000 doses of the vaccine are produced per year for goat pox prevention and control efforts in Taiwan.