豬黴漿菌肺炎不活化疫苗檢驗標準研析

動物用藥品檢定分所

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摘要

豬黴漿菌肺炎於國內約有 30~93%的發生率，傳染性高但死亡率低，長期慢性呼吸道疾病常造成豬隻生長速度減慢，影響上市日期，造成豬農的經濟損失。在本病的防治上，除飼料添加抗生素外，疫苗免疫亦是另一種可行的方法。我國依據動物用藥品檢驗標準第三章第六十九節進行本疫苗逐批檢驗，但國際間新劑型及新檢驗方法不斷開發，再加上實驗動物動保意識抬頭，20 年未修訂之檢驗方法已然不符合國際趨勢。為與國際接軌，本研究先分析我國與歐盟、日本、美國等國家檢驗標準的差異，並利用新開發的方法測試目前已上市許可的疫苗，確認可行後提送檢驗標準修正草案，新修訂之豬黴漿菌肺炎不活化疫苗檢驗標準於 108 年 6 月 24 日正式公告施行。

Analysis of inspection standards for an inactivated vaccine against *Mycoplasma hyopneumoniae*

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Abstract

The prevalence rate of swine enzootic pneumonia, which is caused by infections from the bacterium, *Mycoplasma hypopneumoniae*, is about 30-93% in Taiwanese swine populations. The disease is characterized by high infectivity but low mortality rates. Long-term chronic respiratory diseases often negatively impact pig growth, thus delaying market dates and causing economic losses for farmers. For the prevention and control of this disease, vaccine delivery is another feasible method complementing the common process of adding antibiotics to feed. We have inspected the inactivated vaccine developed against *M. hypopneumoniae*, batch-by-batch according to Chapter 3, Section 69 of the "Inspection Standards for Veterinary Drugs" for many years however new inspection methods are continuously being developed, and there is a rising awareness for the ethical treatment of laboratory animals. Thus, the current inspection standards, having been unrevised for 20 years, are no longer in line with international standards and trends. In order to be in line with international standards, this study started by comparing inspection methods from Taiwan, the EU, Japan and the USA. We also tested currently approved vaccines using newly developed inspection methods. After the newly developed methods confirmed the effectiveness and safety of the vaccine, we submitted the revised draft of the inspection standards. New revised inspection standards for the *Mycoplasma hyopneumoniae* inactivated vaccine was implemented with an official announcement on June 24th, 2019