

水產魚用疫苗檢驗標準研析

動物用藥品檢定分所

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摘要

台灣水產養殖業魚種眾多，多屬溫水魚種，如石斑、烏魚、吳郭魚及鱸魚等，業者養殖技術優良，但疫病問題易造成嚴重經濟損失，常以抗生素及化學物質控制，防疫政策應以前端主動免疫逐步取代後端藥物給予，亦減少民眾食安疑慮。水產疫苗研發、上市及推廣免疫便成為熱門指標。目前我國已取得動物用藥品許可證上市之水產疫苗種類共計有2種，疫苗病原種類包含石斑魚虹彩病毒（Grouper iridovirus）及魚型鏈球菌（*Streptococcus iniae*），國內研發水產疫苗相關學術機構及研究單位眾多，此研究彙整國際間水產疫苗檢驗標準，包含日本、韓國、歐盟及中國大陸等，各國水產疫苗給予方式包含浸泡方式、經口投予、肌肉注射及腹腔注射等，疫苗病原種類則廣泛包含虹彩病毒、神經壞死病毒、乳酸球菌、魚型鏈球菌、無乳鏈球菌、弧菌、發光菌及愛德華氏菌等，即使相同疫苗病原，但免疫於不同魚種時其效力試驗判定方法及標準亦不相同，非一體適用，由於各國盛行病原種類及其感染毒（菌）株別皆不相同，有其地域區別，國外欲輸入我國進行檢驗登記之水產疫苗，若要使用於本國水產養殖產業，是否真能提供足夠之保護效力，仍須進行委託試驗以台灣本土分離株進行效力試驗或其抗體力價測定方式加以評估，但其原廠廠規之檢測評估方式，仍可做為國家水產疫苗檢驗之參考。

Inspection standards for the analysis of aquatic vaccines

Chun-Ta Lin

Abstract

Taiwan has a variety of warm-water fishes that are commercially reared within the aquaculture industry such as grouper, mullet, tilapia and various bass species. Although aquatic fish rearing and breeding techniques in Taiwan are well run and qualified, there still are some recurrent aquatic disease problems that lead to significant economic losses. Antibiotics and other chemical compounds are typically applied to control aquatic disease outbreaks, but an ideal epidemic prevention policy we should entail active front-end animal immunization instead of back-end administration of medicine, thereby reducing public health risks. Indeed, aquatic vaccine development, manufacturing, and commercialization has become economically viable in recent years. Currently, two aquatic vaccines for Grouper iridovirus and *Streptococcus iniae* have been approved and are available in the Taiwanese market. Our inspection standards for aquatic animal vaccines will adopt and consolidate those from Japan, South Korea, the European Union and China. The methods for vaccine administration in those countries include soaking and oral administration, as well as intramuscular and intraperitoneal injections. The disease pathogens targeted in these countries include red sea bream iridovirus, nervous necrosis virus, *Lactococcus garvieae*, *Streptococcus iniae*, *Streptococcus dysgalactiae*, *Vibrio anguillarum*, *Photobacterium damsela subsp. piscicida* and *Edwardsiella tarda*. Nevertheless, a specific pathogen vaccine will have different specific efficacies, efficiencies and standards for immunization dependent on the fish species. Variations in vaccine host used during development, strain variations of pathogens based on geography, as well as other factors, present additional obstacles for the inspection and registration of potentially imported aquatic vaccines. Imported vaccines will thus have to be first tested in field trials on Taiwanese strains and fish species for efficacy, effectiveness, and antibody titers, to determine whether the results are comparable to original tested conditions. The original imported vaccine test results can thus serve as a reference for the inspection of domestically developed aquaculture vaccines.