

Ready to market vaccine for pangasius catfish

Recognised as the only pharmaceutical company focusing on aquaculture, PHARMAQ started the 'pangasius project' in 2006. The objective is to reduce the use of antibacterials and mortality, and improve food safety and environment in the pangasius farming sector.

Over five years, scientists from Can Tho University, University of Stirling Bayer Vietnam and PHARMAQ have collaborated in developing, documenting and registering efficacious vaccines for the pangasius fish. The wet lab set up in Hong My hatchery in Dong Thap Province was used for conducting clinical experiments, which formed the basis for vaccine development. At the end of 2008, the optimal vaccine formula was selected for production in Overhalla in Norway. Field trials followed by working with farmers in the Mekong Delta. The result is 'ALPHA JECT® Panga1, an oil based vaccine against bacillary necrosis in pangasius (BNP), caused by the bacteria *Edwardsiella ictaluri*.

At a seminar for the local industry, the PHARMAQ team from Norway and Vietnam announced that Vietnam's Department of Animal Health (DAH) is expected to allow commercial import license for the purpose of field observation of the vaccine ALPHA JECT® Panga 1.

In his welcome address to farmers, technicians and government representatives, Dr. Nguyen Huu Dung, Vice Chairman of VASEP said that he was pleased with the developments and that a company was established in Vietnam to help look at farmers' woes. The urgency for a vaccination program was justified by the survey conducted by Dr Tu Thanh Dung, Can Tho University in the Mekong Delta. She said that in the case of bacillary necrosis of the pangasius, the disease is acute in fingerlings and juvenile fish. Farmers have used various antibiotics for disease treatment and over the years, these have led to multiple antibiotic resistance to *E. ictaluri*. While the diseases remained, the level of resistance to known antibiotics has been increasing. Naturally, farmers have been increasing the doses of antibiotics.

Approach to developing a vaccine

"To implement a vaccination program, we need to be innovative and do this correctly and be dynamic. We need to adapt to the farmer's needs and have a team spirit between us and the farmers. The development and implementation of a vaccination program is a continuous process and the first approved vaccine will not solve all the problems. For example, the Norwegian salmon industry saw a gradual reduction in operational costs as it moved from using antibiotics to vaccination. We hope to see the same trend in the pangasius industry", said clinical development manager, Vo Thanh Tung, PHARMAQ, Vietnam.

Efficacious laboratory trials were carried out using a total of 880 juveniles at 14g average body weight in controlled lab conditions. These were divided into two groups of 440 each. Fish from one group was injected with a 0.05ml/dose of the vaccine. The other group was injected with sodium chloride. Vaccinated fish from the tanks were challenged at 2, 10 and 20 weeks post vaccination by injecting 0.1ml of a bacterial suspension of *E. ictaluri*; previously isolated from diseased pangasius in Mekong delta. There were two replicates for each treatment and respective controls. A quick response to the vaccine was shown after 2 weeks and the immune period was not less than 20 weeks.

Tung added that the safety trial conducted in lab condition with the required double dose per smaller fish (10g) of 3 different vaccine batches showed no abnormal behaviour, no mortality or any impact on the fish growth but the vaccine will remain in the abdomen of fish as droplets of vaccine and these will disperse as the fish grow.



From left: Vo Thanh Tung, Jan Oppen Berntsen, Dr Tu Thanh Dung (Can Tho University), Kjersti Gravningen, Pham Cong Thanh (technical and marketing manager) and Morten Nordstad.

Dr Kjersti Gravningen, director, Asia said that for markets in EU, USA and Japan, the quality of fish is very important. The company holds a Good Manufacturing Practise (GMP) license, a pharmaceutical standard equivalent to Global Gap for fish farming. The standard ensures that products are consistently produced and controlled according to its specifications. Traceability and transparency is critical in vaccine production.

Gravningen answered several questions likely to be raised by consumers whenever there is a new vaccination program. "Is this safe for human health? The vaccinated fish has been consumer evaluated for safety according to the EU regulations, 37/2010. PHARMAQ vaccines contains inactivated antigens in an emulsion and will not spread any diseases. There will be no need for a withdrawal period. Will there be residues and GMOs? The issue of GMOs (genetically modified) does not arise either. What is the impact on the environment? The product is sterile and the impact on the environment will be much less, than current practices as a healthy fish will have better feed conversion and less wastage of feed."

The evaluation of efficiency and benefits of vaccination was presented by Nguyen Van Nam who has a 80ha farm. His message to the audience of farmers was that the vaccine ALPHA JECT® Panga 1 showed good protection during the outbreak of bacillary necrosis in pangasius. During a field trial conducted in his farm (November 2009) a total of 92,000 fish were vaccinated.

A video showed the steps in implementation of vaccination. On the pond dyke, vaccination is carried out by a trained team around an injection table. Immediately after the injection process, fish are returned to baskets in a water tank which when full are quickly taken on motorbikes for restocking into the respective ponds. Another method is to transfer the injected fish to the ponds using a water trough which runs all the way from the table to the ponds. The third option would be to pump the fish back into the ponds.

"We see this as an important milestone for PHARMAQ and for the pangasius industry in Vietnam. We believe this is an opportunity for the industry to improve on quality. This is the way forward to more sustainable and safe food for the global market. The next step is to implement vaccination in a commercial scale. In the future, we will also invest in new generations of vaccines for Vietnam, as we have learned that fish health management is a dynamic process and we expect new diseases to appear," said Gravningen.