Development and Efficacy of IMMUNIS® MEGAVAC : The First Iridovirus Vaccine for High-Susceptibility Rock Bream (*Oplegnathus fasciatus*)

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Introduction

Megalocytivirus, particularly Red Sea Bream Iridovirus (RSIV) is one of the most devastating viral pathogens in marine aquaculture, causing severe economic losses across East and Southeast Asia. Rock bream (*Oplegnathus fasciatus*) is especially highly susceptible to RSIV infection, exhibiting mortality rates of 80–100% during outbreaks. Despite the significant impact of this disease, no commercially viable vaccine demonstrating clear prophylactic efficacy for rock bream had been successfully developed for more than two decades. To address this critical unmet need, IMMUNIS® MEGAVAC, the world's first iridovirus vaccine for rock bream, was developed using a high-concentration antigen production technology based on a persistently infected *Pagrus major* fin cell (PMF) line combined with a formalin inactivation process.

Since its commercialization in Korea, IMMUNIS® MEGAVAC has shown remarkable market growth and increasing field adoption. Furthermore, the vaccine is being positioned for global expansion, targeting export markets including Indonesia, where field clinical trials are currently underway, as well as Japan, China, Taiwan, and other Southeast Asian countries, based on future regulatory approvals for various susceptible fish species.

Materials and Methods

I. Preparation of vaccines



The Megalocytivirus vaccine, IMMUNIS® MEGAVAC, was manufactured at a GMP-certified facility and used following national batch release approval from the National Fisheries Quality Management Service (NFQS), a governmental agency of the Republic of Korea.

2. Experimental fish and farms



Rock bream (Oplegnathus fasciatus)
Total number of vaccinated fish: 6.4 million



Year	No. of Farms	No. of Vaccinated Fish	Mean Weight of Vaccinated Fish (g)
22'	6	420,000	28.1
23'	22	966,000	79.7
24'	30	1,836,000	95.5
25'	41	3,223,000	67.7
Total	**99**	**6,445,000**	-

From 2022 to 2025, vaccination was conducted in more than 6.4 million rock bream (*Oplegnathus fasciatus*) across approximately 100 aquaculture farms located in Gyeongsangnam-do(GeoJe, TongYeong, SaCheon, NamHae) and Jeollanam-do(YeoSu), Republic of Korea.

3. Vaccine safety and efficacy

To evaluate vaccine safety, fish mortality and abnormal clinical signs were monitored for 2 weeks after vaccination. Vaccine efficacy was evaluated based on the number of fish at the time of vaccination by counting cumulative mortalities or surviving fish at the end of the trial.

Relative percent survival (RPS) was calculated only from farms in which both vaccinated and non-vaccinated control groups were simultaneously maintained under comparable field conditions.

4. Water temperature at vaccination areas

Water temperature data from 2022 to 2025 were obtained from statistical data provided by the National Institute of Fisheries Science (NIFS). Monthly mean water temperatures were calculated and presented for each month from January to December.

References and acknowledgment

❖ National Fisheries Products Quality Management Service (NFQS), Republic of Korea, Guidelines for the testing of veterinary medicines for aquatic animals.

❖ This work was supported by the Technology development Program (RS-2025-24536253) funded by the Ministry of SMEs and Startups (MSS, Korea).

Results and Discussion

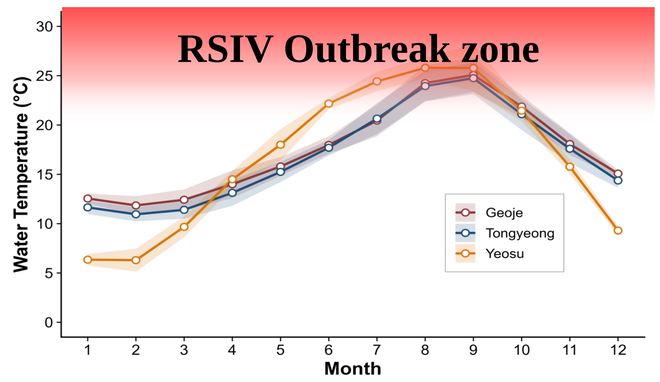


Figure 1. Monthly water temperature profiles at major field trial sites from 2022 to 2025. Solid lines represent mean water temperatures, and shaded ribbons indicate standard deviations (SD). The red shaded area indicates the RSIV outbreak risk zone, generally associated with water temperatures above 20°C.

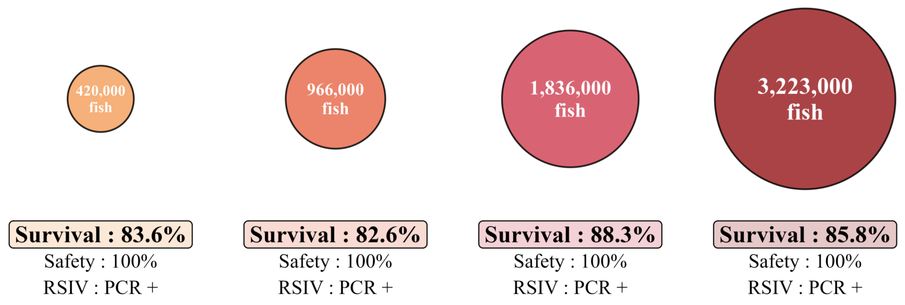


Figure 2. Summary of field vaccine efficacy evaluations conducted from 2022 to 2025 in rock bream aquaculture farms in the Republic of Korea. Bubble size represents the total number of vaccinated fish for each year. Survival indicates the mean survival rate of vaccinated fish under field conditions.

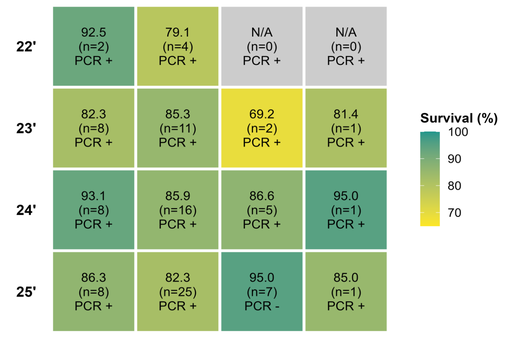


Figure 3. Heat map showing annual mean survival rates (%) of vaccinated rock bream across different aquaculture regions in the Republic of Korea from 2022 to 2025. Values within each cell indicate the mean survival rate, and the number in parentheses represents the number of farms evaluated (n). Gray cells indicate unavailable data (N/A).

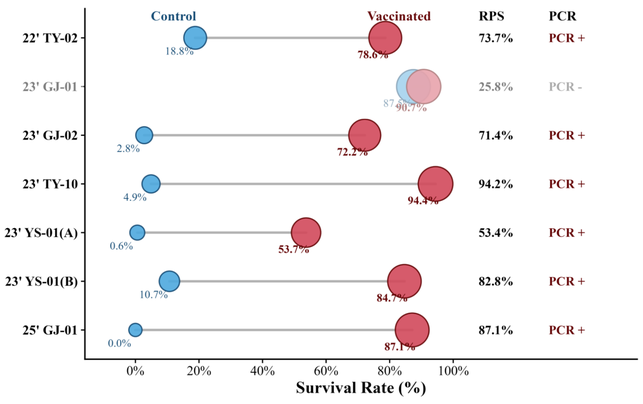


Figure 4. Paired comparison of survival rates between vaccinated and non-vaccinated groups in selected field farms from 2022 to 2025. Blue circles indicate survival rates of non-vaccinated groups, whereas red circles represent vaccinated groups. Circle size is proportional to survival rate (%). Numbers below each circle indicate the corresponding survival percentage. Relative percent survival (RPS) values and RSIV PCR results are shown on the right.

RSIV outbreaks were consistently observed every year in the Republic of Korea from 2022 to 2025. In vaccinated farms, relative percent survival (RPS) ranged from 53.4% to 94.2%, demonstrating strong protective efficacy under field conditions. Since the first field vaccination in 2022, more than 6.4 million rock bream have been vaccinated with IMMUNIS® MEGAVAC, resulting in the survival of over 5.4 million vaccinated fish.

Taken together, as these estimates do not fully account for natural mortality unrelated to RSIV infection, the true vaccine efficacy may be even higher. Nevertheless, appropriate post-vaccination farm management remains important for maintaining stable field protection, supporting the successful field application of the vaccine in commercial aquaculture farms.